Ambulatory blood pressure monitoring

Clinical Policy ID: CCP.1108

Recent review date: 4/2024

Next review date: 8/2025

Policy contains: Ambulatory blood pressure monitoring; masked hypertension; white coat hypertension

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Coverage policy

The use of 24-hour ambulatory blood pressure monitoring is clinically proven and, therefore, may be medically necessary for the diagnosis of hypertension in adult members for any of the following indications (Muntner, 2019; Whelton, 2018):

- Suspected white coat hypertension with a systolic blood pressure > 130 mm Hg but < 160 mm Hg or diastolic blood pressure > 80 mm Hg but < 100 mm Hg after a three-month trial of lifestyle modification.
- Known white coat hypertension with a daytime blood pressure < 130/80 mm Hg on ambulatory or home blood pressure monitoring, when annual monitoring is medically necessary to detect conversion to sustained hypertension.
- Treated hypertension with office readings not at goal and home blood pressure monitoring suggests significant white coat effect.
- Treated hypertension with multiple drug therapies and office blood pressure within 10 mm Hg above goal.
- Suspected masked hypertension with an office blood pressure consistently between 120-129/75-79 mm Hg in untreated members after a three-month trial of lifestyle modification.

- If daytime blood pressure ≥ 130/80 mm Hg on ambulatory or home blood pressure monitoring, annual monitoring is medically necessary to detect conversion to sustained hypertension.
- Suspected masked uncontrolled (treated) hypertension and either elevated home blood pressure readings prior to intensification of antihypertensive drug treatment, or presence of target organ damage or increased overall cardiovascular disease risk and office readings at goal.

The use of 24-hour ambulatory blood pressure monitoring is clinically proven and, therefore, may be medically necessary to assist in the diagnosis of hypertension in pediatric members, using monitors that have been validated in a pediatric population and apply pediatric normative data, for any of the following clinical indications (Flynn, 2017):

- To confirm hypertension when office blood pressure measurements are at:
    - Elevated blood pressure category for 1 year or more, defined as: in children ages 1 to 13 years, in ≥ 90th percentile to < 95th percentile or 120/80 mm Hg to < 95th percentile (whichever is lower); in children ages 13 years or older, 120/< 80 mm Hg to 129/< 80 mm Hg.
    - Stage 1 hypertension defined as: in children ages 1 to 13 years, ≥ 95th percentile to < 95th percentile + 12 mmHg, or 130/80 mm Hg to 139/89 mm Hg (whichever is lower); in children ages 13 years or older, 130/80 mm Hg to 139/89 mm Hg.
    - Stage 2 hypertension after one week, defined as: in children ages 1 to 13 years, ≥ 95th percentile + 12 mm Hg, or ≥ 140/90 mm Hg (whichever is lower); in children ages 13 years or older, ≥ 140/90 mm Hg.
- To confirm treatment effectiveness.
- To diagnose suspected white coat hypertension.
- To routinely assess hypertension severity and determine the presence of abnormal circadian blood pressure patterns in the presence of high-risk conditions, including, but not limited to:
    - Secondary hypertension.
    - Chronic kidney disease or renal abnormalities.
    - Type 1 and type 2 diabetes mellitus.
    - Solid organ transplantation.
    - Obesity.
    - Known or suspected obstructive sleep apnea syndrome.
    - Repaired aortic coarctation.
    - Genetic syndromes associated with hypertension (e.g., neurofibromatosis, Turner syndrome, Williams syndrome, or aortic coarctation).
    - Prematurity.

Limitations

All other uses of ambulatory blood pressure monitoring are investigational/not clinically proven and, therefore, not medically necessary.

The following quality criteria for ambulatory blood pressure monitoring must be met:

- Monitoring is performed for at least 24 hours.
- Automatic readings are set at ≤ 30-minute intervals.
- Monitoring is performed using a U.S. Food and Drug Administration-approved device that has been validated according to international, standardized protocols prior to use.

Repeat ambulatory blood pressure monitoring may be obtained if the first examination has less than 70% of the expected values due to a high number of artifacts.

Routine repeat ambulatory blood pressure monitoring is investigational/not clinically proven and, therefore, not medically necessary.

In a circumstance when ambulatory blood pressure monitoring needs to be performed more than once on a member, the medical necessity and quality criteria described above must be met for each subsequent test.

Alternative covered services

- Office or clinic blood pressure measurement.
- Home blood pressure measurement.

Background

According to the Centers for Disease Control and Prevention (2023), approximately one of every two adults in the United States has hypertension, and only one of four has their blood pressure under control. Among U.S. children, the prevalence of hypertension is 10.4%, with especially high rates for those with children with coarctation of the aorta, solid-organ or stem-cell transplant, chronic kidney disease, and sickle cell disease (Chung, 2023). Primary (essential) hypertension is now identifiable in children and adolescents and is often associated with a positive family history of hypertension or cardiovascular disease, obesity, and lifestyle factors (Flynn, 2017).

Hypertension is classified as follows (systolic/diastolic blood pressure) (Whelton, 2018):

- Normal: < 120 mm Hg/< 80 mm Hg.
- Elevated hypertension: 120 – 139 mm Hg/< 80 mm Hg.
- Stage 1 hypertension: 130 – 139 mm Hg/80 – 89 mm Hg.
- Stage 2 hypertension: ≥ 140 mm Hg/≥ 90 mm Hg.

Accurate blood pressure measurement is essential to correctly classify individuals, ascertain blood pressure-related risk, and guide management. To date, office blood pressure measurements define the relationship between blood pressure and risk but are subject to fluctuations and phenomena such as white coat hypertension (hypertensive in office, normotensive in ambulatory/home setting) or masked hypertension (normotensive in office, hypertensive in ambulatory/home setting). Evidence suggests an association between white coat or masked hypertension and intermediate harmful health outcomes indicating these conditions may not be benign. A diagnosis of white coat hypertension or masked hypertension requires repeated measurements to minimize misclassification of individuals as hypertensive or normotensive (Muntner, 2019).

Masked hypertension and nocturnal blood pressure fall patterns are associated with significantly higher risk of cardiovascular events (Salles, 2016). Nocturnal hypertension and non-dipping may be early markers of masked hypertension (O'Brien, 2016).

Ambulatory blood pressure monitoring is a noninvasive method of obtaining multiple blood pressure readings at regular intervals over a 24-hour (or sometimes 48-hour) period in the person's own living environment. The rationale for its use within carefully selected populations is to provide more precise and accurate blood pressure data that will lead to improved care management and patient outcomes. The purported clinical advantages are to:

- Detect lower blood pressure (white coat hypertension) or higher blood pressure (masked hypertension) out-of-office compared to in-office measurement.
- Determine the presence or absence of normal nocturnal dipping status (i.e., decreases in an individual's blood pressure during nighttime hours or when sleeping).

- Assess the adequacy of blood pressure control in persons taking complex antihypertensive medication regimens.
- Provide detailed information on blood pressure patterns in persons with episodic hypertension, chronic kidney disease, diabetes, and autonomic dysfunction.
- Identify persons with apparently refractory hypertension but relatively little to no target organ damage.
- Confirm hypertension in patients in whom there is a large discrepancy between clinic and home blood pressure measurements.

In the United States, several ambulatory blood pressure monitors have been cleared for marketing via the 510(k) process (U.S. Food and Drug Administration, 2024). However, monitors that have not undergone validation testing or U.S. Food and Drug Administration clearance can also be sold in the United States, but few have been formally validated in children (Flynn, 2017).

Findings

The European Society of Hypertension found sufficient evidence to recommend ambulatory blood pressure monitoring to confirm the presence or absence of white coat hypertension in patients with grade 1 hypertension, masked hypertension, clinically suspected nocturnal blood pressure phenotypes, and true resistant hypertension. Other indications include diagnosing hypertension in the presence of large variability of office blood pressure measurement, evaluating 24-hour blood pressure control (especially in high-risk individuals), and assessing symptoms of hypotension (Mancia, 2023).

The American College of Cardiology/American Heart Association recommends ambulatory blood pressure monitoring, in addition to clinic blood pressure monitoring, to detect white coat effect and masked hypertension (Whelton, 2018). The National Institute for Health and Care Excellence (2023) issued similar recommendations.

There is a lack of consensus among guidelines regarding the definition of hypertension in adult populations according to ambulatory blood pressure monitoring (Mancia, 2023; National Institute for Health and Care Excellence, 2023). Guidelines apply thresholds based on a definition of hypertension (e.g., office blood pressure > 140/90 mm Hg) from clinical trials that examined the benefits of treating hypertension. Less robust data exist to support basing treatment guidelines on ambulatory blood pressure measurement (Mancia, 2023).

The American Academy of Pediatrics found ambulatory blood pressure monitoring was more accurate than clinic measurement for diagnosing hypertension and more reproducible than either casual or home blood pressure measurements in children. The Academy identified several high-risk conditions for which ambulatory blood pressure monitoring may be useful (Flynn, 2017).

In 2016, we identified one additional systematic review for the United States Preventive Services Task Force that updated a 2007 systematic review on the benefits and harms of screening for hypertension in adults and summarized evidence on rescreening intervals and diagnostic and predictive accuracy for cardiovascular events of different blood pressure methods (Piper, 2015). The United States Preventive Services Task Force and the Canadian Hypertension Education Program now recommend ambulatory blood pressure monitoring to confirm initially elevated blood pressure measured by office-based screening methods to avoid potential over-diagnosis of isolated clinic hypertension and harms of unnecessary treatment (Cloutier, 2015; Siu, 2015). These results do not change earlier findings; therefore, no changes to the current policy are warranted.

Current guidelines acknowledge the diagnostic superiority of 24-hour ambulatory blood pressure monitoring for its ability to identify sustained hypertension by excluding white coat hypertension, identifying the presence of episodic or masked hypertension, and providing additional prognostic information from nocturnal patterns of blood pressure (Flynn, 2017; O'Brien, 2016). Given the known risks associated with inadequately controlled hypertension, ambulatory blood pressure monitoring may be beneficial when longer measurement periods are

needed to diagnose hypertension phenotypes to determine an appropriate diagnosis, and the information would alter care management. There remains a lack of consensus on the best method for identifying individuals who would most likely benefit from ambulatory blood pressure monitoring screening for conditions other than white coat hypertension.

The use of ambulatory blood pressure monitoring for diagnosing masked hypertension warrants further consideration, as a significant portion of untreated and treated persons with non-elevated clinic blood pressure have masked hypertension and abnormal nocturnal blood pressure profiles.

In 2017, we identified several indices that were developed to identify candidates for ambulatory blood pressure monitoring who have normal office blood pressure, but they require further validation before routine clinical use (Bromfield, 2016; Schwartz, 2016; Sheppard, 2016). Masked hypertension and masked uncontrolled hypertension are more likely in individuals of African descent, with increased cardiovascular risk and disease states (e.g., diabetes, chronic renal failure, and metabolic syndrome), older persons, males, shortened sleep time, and obstructive sleep apnea (Colantonio, 2017; Franklin, 2017; Thomas, 2017; Wang, 2017). Persons with prehypertension are more likely to have masked hypertension than those with optimal blood pressure and frequently develop target organ damage prior to transitioning to sustained hypertension (Colantonio, 2017; Franklin, 2017).

It is reasonable to apply ambulatory blood pressure monitoring to individuals with normal or elevated (prehypertensive) casual measurements when there is a clinical suspicion of hypertension (e.g., presence of left ventricular hypertrophy) to minimize misclassification of such individuals as normotensive or with controlled hypertension.

In 2018, we added longitudinal data from the Jackson Heart Study (Ravenell, 2017) and updated guidelines from the American Academy of Pediatrics (Flynn, 2017), the American College of Cardiology/American Heart Association (Whelton, 2018), and Canadian Hypertension Education Program (Leung, 2017). Few data have established thresholds for ambulatory hypertension based on U.S. populations. Ravenell et al provides new information derived from an African American population, and both guidelines incorporate updated definitions of ambulatory hypertension while pointing out the need for practitioners to interpret these values in the context of their own patient populations. The guidelines expand the roles for ambulatory blood pressure monitoring, and the policy was modified to reflect these new changes.

In 2019, we added a new cost effectiveness analysis, which found ambulatory blood pressure measurement was the dominant diagnostic strategy of choice over clinical or home blood pressure measurement in primary care settings for most U.S. adults across all age groups regardless of initial screening results (Beyhaghi, 2019). These findings are consistent with previous policy findings. No policy changes are warranted. The policy ID was changed from CP# 04.01.03 to CCP.1108.

In 2020, the American Heart Association updated their scientific statement on blood pressure measurement (Muntner, 2019, update of Pickering, 2005). Their recommendations for ambulatory blood pressure monitoring align with those of Whelton (2018). We added requirements for lifestyle modification and annual monitoring for suspected white coat hypertension and masked hypertension.

In 2021, we updated the references, including guidance from the National Institute for Health and Care Excellence. We added a U.S. Preventive Services Task Force evidence synthesis on screening for hypertension in children and adolescents (Gartlehner, 2020). These additions result in no policy changes.

In 2022, we added a results of a series of meta-analyses (52, n = 215,534) performed for the U.S. Preventive Services Task Force, which assessed the benefits and risks of screening adults for hypertension. Sensitivity and specificity were 54% and 90% for initial office-based blood pressure screening; 80% and 55% for office-

based confirmation; and 84% and 60% for home-based confirmation. Authors concluded "major accuracy limitations" exist in effective screening (Guirguis-Blake, 2021).

A systematic review/meta-analysis of 26 studies determined that 7% of patients were diagnosed with white coat hypertension after automated office blood pressure measurement versus 14% after manual measurement. As 13% of patients had masked hypertension after automated measurement, this technique needs to be further refined (Bo, 2021).

In 2023, we updated the reference from the National Institute for Health and Care Excellence, and added several new large reviews, including:

- A systematic review of 16 studies (n = 10,158) showing high sensitivity and specificity (96.2% and 94.0%) of blood pressure measurements using automated devices detecting atrial fibrillation in office settings, but accuracy of detection using ambulatory measurements is not well studied (Tang, 2022).
- A systematic review/meta-analysis of 15 studies (n = 5,729) showed a "slight to fair" ability to reproduce masked hypertension using ambulatory or home blood pressure monitoring, with somewhat better results using ambulatory monitoring. Reproduction may be reduced due to inaccurate office-based results (Antza, 2022).
- A systematic review of six studies indicated that among hypertensive pregnant women, outcomes risks were similar between self-monitoring and clinic-based monitoring of blood pressure (Yeh, 2022).

In 2024, we updated the references from the National Institute for Health and Care Excellence and the European Society of Hypertension with no policy changes warranted.

References

On January 8, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "blood pressure monitoring, ambulatory" (MeSH), "hypertension/diagnosis" (MeSH), and "ambulatory blood pressure monitoring." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

5/2014: initial review date and clinical policy effective date: 10/2014

4/2015: Policy references updated.

4/2016: Policy references updated.

4/2017: Policy references updated.

4/2018: Policy references updated. Policy indications expanded for ambulatory blood pressure monitoring based on new guidelines.

4/2019: Policy references updated. Policy ID changed.

4/2020: Policy references updated. Policy indications expanded to Medicare members.

4/2021: Policy references updated.

4/2022: Policy references updated.

4/2023: Policy references updated.

4/2024: Policy references updated.