



CLINICAL MEDICAL POLICY	
Policy Name:	Ambulatory Blood Pressure Monitoring
Policy Number:	MP-090-MD-DE
Responsible Department(s):	Medical Management
Provider Notice Date:	10/02/2019; 07/15/2018
Issue Date:	11/04/2019; 08/15/2018
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Annual Approval Date:	09/10/2020
Revision Date:	09/10/2020
Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 10

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary ambulatory adult and pediatric blood pressure monitoring for suspected white coat hypertension.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Hypertension- is also known as high blood pressure, is a long term medical condition in which the blood pressure in the arteries is persistently elevated.

Ambulatory blood pressure monitoring- a portable device that takes and records blood pressure intermittently in 24 hour cycles, during normal daily activities. These devices may be fully automated, thereby they inflate at preprogrammed intervals. Or the devices can be semi-automated and are patient activated.

Nocturnal Dip-A significant day-night difference in blood pressure of more than 10% or more than 10/5 mm Hg.

PROCEDURES

The following medical necessity criteria for the diagnosis and management of hypertension must be met.

A. Adult Criteria

- 1) For patients with suspected white coat hypertension, which is defined as an average office blood pressure of systolic blood pressure greater than 130 mm Hg but less than 160 mm Hg or diastolic blood pressure greater than 80 mm Hg but less than 100 mm Hg on two separate clinic/office visits with at least two separate measurements made at each visit with at least two blood pressure measurements taken outside the office which are less than 130/80 mm Hg.
- 2) Automated ABPM is considered medically necessary in cases of suspected masked hypertension. The patient must have suspected masked hypertension, which is defined as an average office blood pressure between 120 mm Hg and 129 mm Hg for systolic blood pressure or between 75 mm Hg and 79 mm Hg for diastolic blood pressure on two separate clinic/office visits with at least two separate measurements made at each visit and with at least two blood pressure taken outside the office which are greater than or equal to 130/90 mm Hg.

B. Pediatric/Adolescents Criteria

- 1) Confirming the diagnosis of hypertension including differentiating true hypertension from "white coat" hypertension:
 - a. The physician has performed at least three blood pressure measurements at least 1 week apart in the office; AND
 - b. Blood pressure measurements by non-physicians (e.g., nurse, technician) have been done (initial measurement, 2nd measurement in 1-2 weeks, and 3rd measurement in 3 months), and stage one hypertension readings have been obtained.
 - c. Threshold levels for the diagnosis of hypertension should be based on pediatric normative data, which includes gender and height specific values derived from large pediatric populations

ABPM in children and adolescents should be used by experts in the field of pediatric nephrology and pediatric cardiology who are experienced in its use and interpretation.

Note: Coverage for ABPM is limited to one monitoring session per calendar year.

In addition, automated ABPM testing must:

- A. Must be of a duration of at least 24 hours but no more than 48 hours; AND

- B. The automated device must be performed using an FDA-approved machine that has been validated; AND
- C. The device must be capable of producing standardized plots of blood pressure measurements for 24 hours with daytime and nighttime windows and normal blood pressure bands demarcated; AND
- D. The findings from the ABPM will result in therapeutic decisions; AND
- E. The findings must be read by the treating physician or treating non-physician practitioner

2. Contraindications

ABPM devices should not be used

- On neonates and children under the age of 3 years
- On patients with severe clotting disorders
- On patients with severe cardiac rhythm abnormalities (e.g., atrial fibrillation)
- On patients with latex allergy

3. When the automated ABPM services are not covered

The use of automated ABPM for any condition not listed above and will be considered not medically necessary. Examples of noncovered conditions include but are not limited to:

- Blood pressure monitoring in patients with heart failure; OR
- Blood pressure monitoring of pregnant women who do not meet the criteria above; OR
- The diagnosing of malignant hypertension; OR
- In patients with irregular cardiac arrhythmias; OR
- To evaluate the effectiveness of blood pressure treatment; OR
- For the evaluation of patients with uncomplicated hypertension or to screen for hypertension

4. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

5. Place of Service

The place of service for ABPM is outpatient.

GOVERNING BODIES APPROVAL

Examples of FDA approved ABPM, not all inclusive

- Pressure Trak Ambulatory Blood Pressure Measurement System
FDA-approved indication: A non-invasive oscillometric ambulatory blood pressure monitor that is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult patient's systolic and diastolic blood pressures over an extended period of time.
- ABP-2000 G-3
FDA-approved indication: A non-invasive oscillometric ambulatory blood pressure monitor that is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure a patient's systolic and diastolic blood pressures over an extended period of time.
- Welch Allyn ABPM 6100
FDA-approved indication: A non-invasive oscillometric ambulatory blood pressure monitor that is intended for use 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.

Additional information is available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm>.

The Centers for Medicare & Medicaid Services (CMS) issued a Decision Memo for Ambulatory Blood Pressure Monitoring (ABPM) (CAG-00067R2) on July 2, 2019. The memo states that CMS has determined that there is sufficient evidence to expand coverage for ABPM. The memo alters the blood pressure criteria for patients with suspected white coat hypertension and expands coverage for patients with suspected masked hypertension. In addition, the memo documents that coverage for other indications for ABPM are at the discretion of the Medicare Administrative Contractors.

CODING REQUIREMENTS

Procedure Codes

CPT Codes	Description
93784	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

Diagnosis Codes

ICD-10 Code	Description
R03.0	Elevated blood-high pressure reading, without diagnosis of hypertension
I10	Essential (primary) hypertension

* ABPM will not be reimbursed for any other medical condition without Medical Director Approval.

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

Hypertension

In the United States, one of every three adults has high blood pressure, but only half of the people with high blood pressure have the condition under control. Nearly 1 of 3 American adults has prehypertension (blood pressure numbers that are higher than normal, but not yet in the high blood pressure range). High blood pressure costs the nation \$46 billion per year. This total includes the cost of health care services, medication to treat high blood pressure, and missed days of work (CDC). Furthermore, more than 360,000 American deaths in 2013 included high blood pressure as a primary or contributing cause. High blood pressure develops more often and at an earlier age in blacks than in whites and Hispanics. Complications from hypertension include but are not limited to coronary artery disease, stroke, heart failure, peripheral vascular disease, vision loss, chronic kidney disease, and dementia.

Blood pressure monitoring can be obtained with the use of an ambulatory blood pressure monitor (ABPM), home blood pressure monitor (HBPM), and in-office reading. ABPM is usually performed over a

24-hour period utilizing a fully automated blood pressure device. The device records blood pressure readings at frequent intervals during the day and night in order to determine the variability of a patient's BP. The device can be fully automated or semi-automated and is a portable battery-operated monitor worn on the hip and connected to an inflatable blood pressure cuff. The cuff will inflate and deflate at pre-determined intervals, typically every 15 to 30 minutes during the day and every 30 minutes during the night. The recorded blood pressures are retrieved by a health care professional for interpretation. The results are used as a tool to establish a diagnosis of hypertension to avoid the use of life-long antihypertensive therapy.

The advantages of using ABPM are that it is fully automated and noninvasive, BP is recorded over an extended period of time, and the ABPM has the ability to identify BP patterns that cannot be identified with office BP readings. The ABPM has been used in situations to confirm white coat hypertension, resistant hypertension, masked hypertension, nocturnal hypertension, in pregnancy, to monitor drug therapy, ambulatory hypotension, and autonomic dysfunction, underlying systemic abnormalities.

In 2015, the United States Preventive Services Task Force (USPSTF) published the 'A' recommendation that individuals 18 years of age and older are to be screened for hypertension. The recommendation states that screening for high blood pressure in adults aged 18 years or older and that obtaining measurements *outside* of the clinical setting for diagnostic confirmation should be done before starting treatment. The Task Force states that ABPM and home blood pressure monitoring may be used to confirm a diagnosis of hypertension after initial screening. However, they found that there was solid evidence that ABPM is the best method for diagnosing hypertension.

The American College of Cardiology (2017) stressed the importance of accurate measurement of blood pressure in order to categorize the level of BP, ascertain BP-related CVD risk, and to guide the management of elevated BP. The authors recommended the use of either ABPM or HBPM (home based blood pressure monitoring) for diagnosing and monitoring white coat hypertension, to detect transition from white coat hypertension to sustained hypertension.

The National Institute for Health and Care Excellence (NICE) recommends that if a patient's blood pressure is 140/90 mm Hg or higher, an ABPM should be offered to confirm the diagnosis of hypertension.

Hayes (2008) technology assessment on ABPM found adequate evidence in the peer reviewed literature that ABPM has the potential to distinguish between normotensive patients, patients with white coat hypertension, and patients with sustained hypertension. There was some evidence that the use of ABPM could play a role in determining which uncontrolled hypertensive patients are truly resistant to treatment and have responded to therapy and only have elevated blood pressure in a medical office setting.

The Hayes ratings were assigned as follows:

B rating

- Detection of white coat or isolated clinical hypertension in adult or pregnant women with newly discovered hypertension, who have no evidence of target-organ damage from cardiovascular disease or comorbidities such as diabetes or renal disease;
- Detection of white coat hypertension in adult patients who appear refractory to appropriate antihypertensive therapy, prior to an increase in medication or invasive investigation of the underlying cause.

C rating

- Assisting in determining cardiovascular risk in hypertensive patients and for establishing and monitoring risk of pregnancy complications, such as preeclampsia, that are associated with gestational hypertension.

D rating

- As a method to assess blood pressure in those patients with evidence of severe hypertension that require hospital admission for appropriate diagnosis and treatment.

Masked Hypertension

According to Wang and colleagues (2017), the estimated prevalence of masked hypertension (MH) in the U.S. is approximately 139.3 million adults. Men are affected more frequently than women, it is higher in persons aged 45 years or older, and more common in non-Hispanics and persons with diabetes mellitus.

In 2019, the U.S. Preventive Services Task Force (USPSTF) recommended obtaining blood pressure measurements outside the clinical setting (either ABPM or home BP monitoring) for diagnostic confirmation of high blood pressure (A Grade). The task force specifically states 'In addition to office blood pressure measurement, ABPM and home blood pressure monitoring may be used to confirm a diagnosis of hypertension after initial screening. In 2018, the American College of Cardiology stated that the high prevalence of MH observed in untreated and treated individuals with normal blood pressure in the office supports a wider use of ABPM in routine clinical practice.

In 2015, a study reported on strategies for classifying patients based on office, home, and ambulatory blood pressure measurement. According to the authors, using home instead of ambulatory monitoring misses the high-risk diagnoses of masked or sustained hypertension in over 25% of patients (Zhang et al.). Anstey and colleagues (2017) analyzed data from 333 community-dwelling adults not taking antihypertensive medication with clinic BP >140/90 in the Improving the Detection of Hypertension (IDH) study. Blood pressure was measured with ABPM and home blood pressure monitoring (HBPM), and comparisons of results indicated that ABPM detects many more individuals with MH with an increased cardiovascular disease risk compared to HBPM.

In 2018, the ESH/European Society of Cardiology guideline and 2017 Hypertension Clinical Practice Guidelines recommended screening for masked hypertension. Indications for ABPM include assessment for the presence of white coat hypertension or masked hypertension; monitoring of antihypertensive medication efficacy in treated patient; assessment for the presence of nocturnal hypertension; evaluation of postural, postprandial, and drug-induced hypotension; and assessing hypotension from autonomic dysfunction, which typically requires monitoring during sleep for supine hypertension.

In 2015, NICE issued a quality statement in regards to ABPM. It states that people with suspected hypertension are offered ABPM to confirm a diagnosis of hypertension. The rationale for this statement is that ABPM is the most accurate method for confirming a diagnosis of hypertension, and its use should reduce unnecessary treatment in people who do not have true hypertension. It has been shown to be superior to other methods of multiple blood pressure measurement for predicting blood-pressure-related clinical events.

ABPM Consensus Conference Task Force IV: Adult ABPM Thresholds

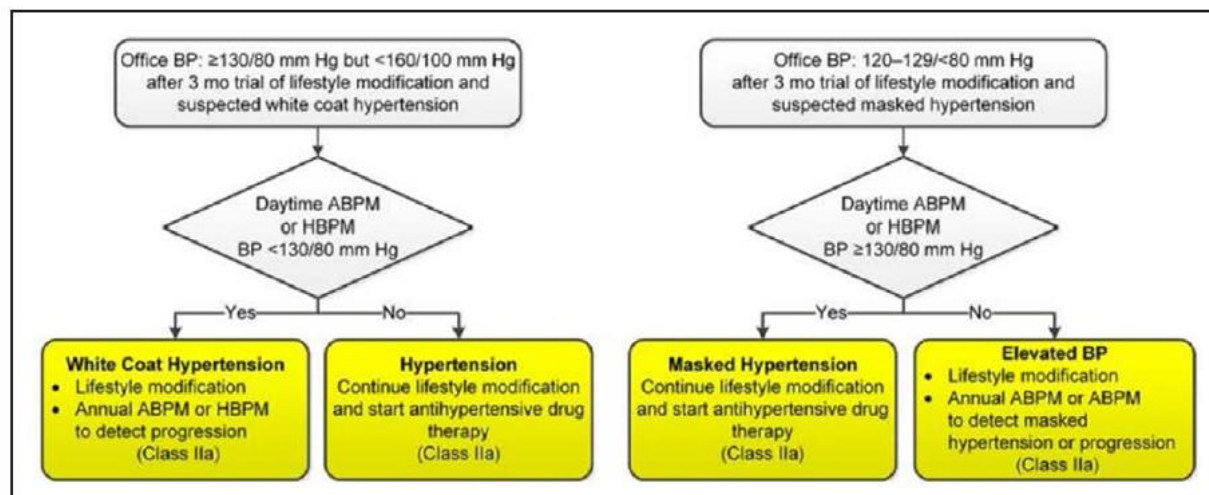
ABPM Measure	95th Percentile	Normotension, mm Hg	Hypertension, mm Hg
24-hour average, mm Hg	132/82	≤130/80	>135/85
Daytime average, mm Hg	138/87	≤135/85	>140/90
Nighttime average, mm Hg	123/74	≤120/70	>125/75

AHA 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%
Prehypertension	>95th percentile	<95th percentile	25%-50%
Ambulatory hypertension	>95th percentile	>95th percentile	25%-50%
Severe ambulatory hypertension	>95th percentile	>95th percentile	>50%

^a The percentage of SBP readings >95th percentile for gender and height.

AHA: American Heart Association Classification of Ambulatory BP Levels in Children



Algorithm to screen for white coat hypertension and masked hypertension in adults not on drug therapy. Copyright ©2017 by the American College of Cardiology Foundation and the American Heart Association.

POLICY SOURCE(S)

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Policy History

Date	Activity
03/27/2018	Initial policy developed
06/19/2018	QI/UM Committee approval
08/15/2018	Provider effective date
09/10/2019	Annual Review Revisions: Revised blood pressure requirement for white coat hypertension; added additional coverage criteria for masked hypertension; removed unbundled codes 93786, 93788, and 93790; updated literature summary, added ICD-10 DX code I10; removed the following criteria-absence of hypertensive end organ damage on physical exam and laboratory testing; revised format; removed hyperlinks from all reference in the Reference section
09/10/2019	QI/UM Committee Review Approval
11/04/2019	Provider Effective Date