MEDICAL POLICY

POLICY TITLE	AUTOMATED AMBULATORY BLOOD PRESSURE MONITORING FOR THE DIAGNOSIS OF HYPERTENSION IN PATIENTS WITH ELEVATED OFFICE BLOOD PRESSURE
POLICY NUMBER	MP-6.002

Original Issue Date (Created):	**7/1/2002**
Most Recent Review Date (Revised):	**6/15/2018**
Effective Date:	**8/1/2018**

I. POLICY

Automated ambulatory blood pressure monitoring (ABPM) 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 section for considerations in pediatric patients):

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

All other uses of ambulatory blood pressure monitoring for patients with elevated office BP, including but not limited to repeated testing in patients with persistently elevated office BP, is considered **investigational,** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

For pediatric patients, the principles of ABPM use to confirm a diagnosis of hypertension are the same as in adults, but there are special considerations as follows (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 AHA guidelines concerning classification of hypertension in pediatric patients using clinic and ambulatory BP are given in the following Table PG1:

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Table PG1. 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%

AHA: American Heart Association; BP: blood pressure; SBP: systolic blood pressure.
[a] The percentage of SBP readings >95th percentile for gender and height.

Cross-reference:

MP-6.026 Durable Medical Equipment

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - Refer to FEP Medical Policy Manual MP-1.01.02, Automated Ambulatory Blood Pressure Monitoring for Diagnosis of Hypertension in Patients with Elevated Office Blood Pressure. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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Ambulatory blood pressure monitors (24-hour sphygmomanometers) are portable devices that continually record blood pressure while the patient is involved in daily activities. There are various types of ambulatory monitors; this policy addresses fully automated monitors, which inflate and record blood pressure at pre-programmed intervals.

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.

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 policy 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 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.”[1]

IV. RATIONALE

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SUMMARY OF EVIDENCE
For individuals with elevated office blood pressure (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.

V. DEFINITIONS

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CIRCADIAN: Pertinent to events that occur at approximately 24-hour intervals, such as certain physiological phenomena.

510 (K) is a premarketing submission made to the FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

HYPERTENSION is a condition in which the blood pressure is higher than 140mm Hg systolic or 90 mm Hg diastolic on three separate readings recorded several weeks apart.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

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VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
93784	93786	93788	93790					

HCPCS Code	Description
A4670	Automatic Blood Pressure Monitoring

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

IX. REFERENCES

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1. *Food and Drug Administration (FDA). Welch Allyn ABPM 1600 pre-market notification: 510(k) summary. 2002; http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K021756. Accessed June 15, 2018.*
2. *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. PMID*
3. *LeFevre F, Aronson N. Technology assessment for ambulatory blood pressure monitoring for adults with elevated office blood pressure decision memo - 10/17/2001. https://www.cms.gov/medicare-coveragedatabase/(S(awjbae45o10tfb2ojw0mjve1))/details/ncddetails.aspx?NCDId=254&NCAId=5&NcaName=Ambulatory+Blood+Pressure+Monitoring&bc=BEAAAAAAEAgA . Accessed June 15, 2018.*

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13. Hansen TW, Kikuya M, Thijs L, et al. Prognostic superiority of daytime ambulatory over conventional blood pressure in four populations: a meta-analysis of 7,030 individuals. J Hypertens. Aug 2007;25(8):1554-1564. PMID 17620947

14. Conen D, Bamberg F. Noninvasive 24-h ambulatory blood pressure and cardiovascular disease: a systematic review and meta-analysis. J Hypertens. Jul 2008;26(7):1290-1299. PMID 18550999

15. Piper MA, Evans CV, Burda BU, et al. Diagnostic and predictive accuracy of blood pressure screening methods with consideration of rescreening intervals: a systematic review for the U.S. Preventive Services Task Force. Ann Intern Med. Feb 3 2015;162(3):192-204. PMID 25531400

16. Blue Cross Blue Shield Association Medical Policy Reference Manual. 1.01.02 Automated Ambulatory Blood Pressure Monitoring for Diagnosis of Hypertension in Patients With Elevated Office Blood Pressure. June 2018.

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X. POLICY HISTORY

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MP 6.002	**CAC 4/29/03**
	CAC 11/30/04
	CAC 10/25/05
	CAC 9/26/06
	CAC 7/31/07
	CAC 7/29/08
	CAC 7/28/09 Consensus Review
	CAC 5/25/10 Adopted BCBSA Criteria
	CAC 4/26/11 Consensus Review, Adopt BCBSA, changed title. No change to policy statements.
	CAC 2/28/12 Revised policy criteria statement from investigational to medically necessary according to BCBSA policy revision. Added FEP variation to FEP Medical Policy. Removed Medicare variation to NCD 20.19.
	CAC 9/24/13 Consensus review. References updated; no change to the policy statements. No coding changes.
	CAC 7/22/14 Consensus review. References updated. Rationale and policy guidelines added. No change to policy statements**.** Added Medicare variation referencing NCD 20.19 Ambulatory Blood Pressure Monitoring.
	CAC 7/22/15 Consensus review. No changes to the policy statements. References and rationale updated. Codes reviewed.
	CAC 7/26/16 Consensus review. No change to policy statements. Reference links updated. Coding reviewed
	Admin update 1/1/17: Product variation section reformatted.
	CAC 9/26/17 Consensus review. Policy statements unchanged. Description/Background, Rationale and Reference sections updated. Coding reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	6/15/18 Consensus. No change to policy statements. References updated. Rationale condensed.

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