

Protocol

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

(10102)

Medical Benefit		Effective Date: 07/01/14	Next Review Date: 03/18
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	

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.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none">• With elevated office blood pressure	Interventions of interest are: <ul style="list-style-type: none">• 24-hour automated ambulatory blood pressure monitoring	Comparators of interest are: <ul style="list-style-type: none">• Office blood pressure measurement• Home blood pressure measurement	Relevant outcomes include: <ul style="list-style-type: none">• Test accuracy• Other test performance measures• Morbid events• Medication use

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 protocol 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. When compared directly to 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 for 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

Policy

Automated ambulatory blood pressure 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), 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 repeat testing in patients with persistently elevated office BP, and monitoring of treatment effectiveness, is considered **investigational**.

Policy Guidelines

For pediatric patients, the principles of ABPM used 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 American Heart Association (AHA) guidelines concerning classification of hypertension in pediatric patients using clinic and ambulatory BP are given in Table 1:

Table 1. American Heart Association 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
Pre hypertension	> 95th percentile	< 95th percentile	25-50%
Ambulatory hypertension	> 95th percentile	> 95th percentile	25-50%
Severe Ambulatory hypertension	> 95th percentile	> 95th percentile	> 50%

BP: blood pressure; SBP: systolic blood pressure

^aPercent of SBP readings that are above 95th percentile for gender and height

Medicare Advantage

ABPM must be performed for at least 24 hours to meet guideline criteria.

ABPM is only **medically necessary** for those patients with suspected white coat hypertension. Suspected white coat hypertension is defined as:

1. Office blood pressure greater than 140/90 mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit;
2. At least two documented blood pressure measurements taken outside the office which are less than 140/90 mm Hg; and
3. No evidence of end-organ damage.

ABPM is considered **investigational** for all other indications.

Medicare Advantage Policy Guidelines

In the rare circumstance that ABPM needs to be performed more than once in a patient, the medical criteria described above must be met for each subsequent ABPM test.

The information obtained by ABPM is medically necessary when it is used to determine the appropriate management of the patient.

Background

ABPM, typically done over a 24-hour period with a fully automated device, provides more detailed 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 compared with the limited number obtained during office measurement.

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 protocol 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 potential 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 nighttime BP; examining diurnal patterns of BP; and/or other potential uses.

Regulatory Status

Many ambulatory blood pressure monitors have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. As an example of an FDA indication, the Welch Allyn ABPM 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. The system is only for measurement, recording, and display. It makes no diagnosis."¹

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

1. U.S. Food and Drug Administration (FDA). Welch Allyn ABPM 1600 pre-market notification: 510(k) summary, 06/27/2002. <http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K021756>. Accessed November 26, 2014.
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.
3. LeFevre F, Aronson N. Technology assessment for ambulatory blood pressure monitoring for adults with elevated office blood pressure decision memo - 10/17/2001. <http://www.cms.gov/medicare-coverage-database/details/nca-details.aspx?NCAId=5&NcaName=Ambulatory+Blood+Pressure+Monitoring&NCDId=254&ncdver=1&IsPopu p=y&bc=AAAAAAAAAgAAAA%3d%3d&>. Accessed November 30, 2014.
4. Imai Y, Hozawa A, Ohkubo T, et al. Predictive values of automated blood pressure measurement: what can we learn from the Japanese population - the Ohasama study. *Blood Press Monit.* Dec 2001; 6(6):335-339. PMID 12055412
5. Verdecchia P. Reference values for ambulatory blood pressure and self-measured blood pressure based on prospective outcome data. *Blood Press Monit.* Dec 2001; 6(6):323-327. PMID 12055410
6. Head GA, Mihailidou AS, Duggan KA, et al. Definition of ambulatory blood pressure targets for diagnosis and treatment of hypertension in relation to clinic blood pressure: prospective cohort study. *BMJ.* 2010; 340:c1104. PMID 20392760
7. Kikuya M, Hansen TW, Thijs L, et al. Diagnostic thresholds for ambulatory blood pressure monitoring based on 10-year cardiovascular risk. *Circulation.* Apr 24 2007; 115(16):2145-2152. PMID 17420350
8. Staessen JA, Beilin L, Parati G, et al. Task force IV: Clinical use of ambulatory blood pressure monitoring. Participants of the 1999 Consensus Conference on Ambulatory Blood Pressure Monitoring. *Blood Press Monit.* Dec 1999; 4(6):319-331. PMID 10602536
9. Muntner P, Lewis CE, Diaz KM, et al. Racial differences in abnormal ambulatory blood pressure monitoring measures: Results from the Coronary Artery Risk Development in Young Adults (CARDIA) study. *Am J Hypertens.* May 2015; 28(5):640-648. PMID 25376639

10. Martin U, Haque MS, Wood S, et al. Ethnicity and differences between clinic and ambulatory blood pressure measurements. *Am J Hypertens*. Jun 2015; 28(6):729-738. PMID 25398890
11. National High Blood Pressure Education Program (NHBPEP) Working Group Report On Ambulatory Blood Pressure Monitoring U.S. DHHS In: Program. NHBPE, ed1992.
12. Fagard RH, Staessen JA, Thijs L, et al. Response to antihypertensive therapy in older patients with sustained and nonsustained systolic hypertension. Systolic Hypertension in Europe (Syst-Eur) Trial Investigators. *Circulation*. Sep 5 2000; 102(10):1139-1144. PMID 10973843
13. Staessen JA, Thijs L, Fagard R, et al. Predicting cardiovascular risk using conventional vs. ambulatory blood pressure in older patients with systolic hypertension. Systolic Hypertension in Europe Trial Investigators. *JAMA*. Aug 11 1999; 282(6):539-546. PMID 10450715
14. 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
15. Gustavsen PH, Hoegholm A, Bang LE, et al. White coat hypertension is a cardiovascular risk factor: a 10-year follow-up study. *J Hum Hypertens*. Dec 2003; 17(12):811-817. PMID 14704724
16. Khattar RS, Senior R, Lahiri A. Cardiovascular outcome in white-coat versus sustained mild hypertension: a 10-year follow-up study. *Circulation*. Nov 3 1998; 98(18):1892-1897. PMID 9799210
17. Ohkubo T, Kikuya M, Metoki H, et al. Prognosis of "masked" hypertension and "white-coat" hypertension detected by 24-h ambulatory blood pressure monitoring 10-year follow-up from the Ohasama study. *J Am Coll Cardiol*. Aug 2 2005; 46(3):508-515. PMID 16053966
18. Strandberg TE, Salomaa V. White coat effect, blood pressure and mortality in men: prospective cohort study. *Eur Heart J*. Oct 2000; 21(20):1714-1718. PMID 11032699
19. Ugajin T, Hozawa A, Ohkubo T, et al. White-coat hypertension as a risk factor for the development of home hypertension: the Ohasama study. *Arch Intern Med*. Jul 11 2005; 165(13):1541-1546. PMID 16009871
20. Verdecchia P, Porcellati C, Schillaci G, et al. Ambulatory blood pressure. An independent predictor of prognosis in essential hypertension. *Hypertension*. Dec 1994; 24(6):793-801. PMID 7995639
21. Gaborieau V, Delarche N, Gosse P. Ambulatory blood pressure monitoring versus self-measurement of blood pressure at home: correlation with target organ damage. *J Hypertens*. Oct 2008; 26(10):1919-1927. PMID 18806615
22. Salles GF, Cardoso CR, Muxfeldt ES. Prognostic influence of office and ambulatory blood pressures in resistant hypertension. *Arch Intern Med*. Nov 24 2008; 168(21):2340-2346. PMID 19029499
23. Cuspidi C, Rescaldani M, Tadic M, et al. White-coat hypertension, as defined by ambulatory blood pressure monitoring, and subclinical cardiac organ damage: a meta-analysis. *J Hypertens*. Jan 2015; 33(1):24-32. PMID 25380162
24. Martin CA, McGrath BP. White-coat hypertension. *Clin Exp Pharmacol Physiol*. Jan 2014; 41(1):22-29. PMID 23682974
25. Fagard RH, Cornelissen VA. Incidence of cardiovascular events in white-coat, masked and sustained hypertension versus true normotension: a meta-analysis. *J Hypertens*. Nov 2007; 25(11):2193-2198. PMID 17921809
26. 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
27. Verdecchia P, Reboldi GP, Angeli F, et al. Short- and long-term incidence of stroke in white-coat hypertension. *Hypertension*. Feb 2005; 45(2):203-208. PMID 15596572
28. Pickering TG, Shimbo D, Haas D. Ambulatory blood-pressure monitoring. *N Engl J Med*. Jun 1 2006; 354(22):2368-2374. PMID 16738273

29. Staessen JA, Asmar R, De Buyzere M, et al. Task Force II: blood pressure measurement and cardiovascular outcome. *Blood Press Monit.* Dec 2001; 6(6):355-370. PMID 12055415
30. 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
31. Hodgkinson J, Mant J, Martin U, et al. Relative effectiveness of clinic and home blood pressure monitoring compared with ambulatory blood pressure monitoring in diagnosis of hypertension: systematic review. *BMJ.* 2011; 342:d3621. PMID 21705406
32. Stergiou GS, Bliziotis IA. Home blood pressure monitoring in the diagnosis and treatment of hypertension: a systematic review. *Am J Hypertens.* Feb 2011; 24(2):123-134. PMID 20940712
33. Lovibond K, Jowett S, Barton P, et al. Cost-effectiveness of options for the diagnosis of high blood pressure in primary care: a modelling study. *Lancet.* Oct 1 2011; 378(9798):1219-1230. PMID 21868086
34. Addison C, Varney S, Coats A. The use of ambulatory blood pressure monitoring in managing hypertension according to different treatment guidelines. *J Hum Hypertens.* Aug 2001; 15(8):535-538. PMID 11494091
35. Staessen JA, Byttebier G, Buntinx F, et al. Antihypertensive treatment based on conventional or ambulatory blood pressure measurement. A randomized controlled trial. *Ambulatory Blood Pressure Monitoring and Treatment of Hypertension Investigators. JAMA.* Oct 1 1997; 278(13):1065-1072. PMID 9315764
36. Staessen JA, Den Hond E, Celis H, et al. Antihypertensive treatment based on blood pressure measurement at home or in the physician's office: a randomized controlled trial. *JAMA.* Feb 25 2004; 291(8):955-964. PMID 14982911
37. Aylett M, Marples G, Jones K. Home blood pressure monitoring: its effect on the management of hypertension in general practice. *Br J Gen Pract.* Sep 1999; 49(446):725-728. PMID 10756615
38. Rickerby J. The role of home blood pressure measurement in managing hypertension: an evidence-based review. *J Hum Hypertens.* Jul 2002; 16(7):469-472. PMID 12080430
39. Weisser B, Mengden T, Dusing R, et al. Normal values of blood pressure self-measurement in view of the 1999 World Health Organization-International Society of Hypertension guidelines. *Am J Hypertens.* Aug 2000; 13(8):940-943. PMID 10950404
40. Verdecchia P, Palatini P, Schillaci G, et al. Independent predictors of isolated clinic ('white-coat') hypertension. *J Hypertens.* Jun 2001; 19(6):1015-1020. PMID 11403348
41. Stergiou GS, Karpettas N, Panagiotakos DB, et al. Comparison of office, ambulatory and home blood pressure in children and adolescents on the basis of normalcy tables. *J Hum Hypertens.* Apr 2011; 25(4):218-223. PMID 20520632
42. Urbina E, Alpert B, Flynn J, et al. Ambulatory blood pressure monitoring in children and adolescents: recommendations for standard assessment: a scientific statement from the American Heart Association Atherosclerosis, Hypertension, and Obesity in Youth Committee of the Council on Cardiovascular Disease in the Young and the Council for High Blood Pressure Research. *Hypertension.* Sep 2008; 52(3):433-451. PMID 18678786
43. Valent-Moric B, Zigman T, Zaja-Franulovic O, et al. The importance of ambulatory blood pressure monitoring in children and adolescents. *Acta Clin Croat.* Mar 2012; 51(1):59-64. PMID 22920003
44. Sorof JM, Portman RJ. White coat hypertension in children with elevated casual blood pressure. *J Pediatr.* Oct 2000; 137(4):493-497. PMID 11035827
45. Matsuoka S, Kawamura K, Honda M, et al. White coat effect and white coat hypertension in pediatric patients. *Pediatr Nephrol.* Nov 2002; 17(11):950-953. PMID 12432440
46. National Institute for Health and Care Excellence. Hypertension in adults: diagnosis and management (NICE clinical guideline 127). Aug 2011 (updated Oct 2013); www.nice.org.uk/guidance/CG127. Accessed July 6, 2016.

47. Daskalopoulou SS, Rabi DM, Zarnke KB, et al. The 2015 Canadian Hypertension Education Program recommendations for blood pressure measurement, diagnosis, assessment of risk, prevention, and treatment of hypertension. *Can J Cardiol*. May 2015; 31(5):549-568. PMID 25936483
48. Flynn JT, Daniels SR, Hayman LL, et al. Update: ambulatory blood pressure monitoring in children and adolescents: a scientific statement from the American Heart Association. *Hypertension*. May 2014; 63(5):1116-1135. PMID 24591341
49. Mancia G, Fagard R, Narkiewicz K, et al. 2013 ESH/ESC guidelines for the management of arterial hypertension: the Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). *Eur Heart J*. Jul 2013; 34(28):2159-2219. PMID 23771844
50. O'Brien E, Asmar R, Beilin L, et al. European Society of Hypertension recommendations for conventional, ambulatory and home blood pressure measurement. *J Hypertens*. May 2003; 21(5):821-848. PMID 12714851
51. O'Brien E, Asmar R, Beilin L, et al. Practice guidelines of the European Society of Hypertension for clinic, ambulatory and self blood pressure measurement. *J Hypertens*. Apr 2005; 23(4):697-701. PMID 15775768
52. O'Brien E, Parati G, Stergiou G, et al. European Society of Hypertension position paper on ambulatory blood pressure monitoring. *J Hypertens*. Sep 2013; 31(9):1731-1768. PMID 24029863
53. Parati G, Stergiou G, O'Brien E, et al. European Society of Hypertension practice guidelines for ambulatory blood pressure monitoring. *J Hypertens*. Jul 2014; 32(7):1359-1366. PMID 24886823
54. National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents. The Fourth Report on the diagnosis, evaluation, and treatment of high blood pressure in children and adolescents. *Pediatrics*. Aug 2004; 114(2 Suppl 4th Report):555-576. PMID 15286277
55. Chobanian AV, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. *JAMA*. May 21, 2003; 289(19):2560-2572. PMID 12748199
56. United States Preventive Services Task Force. High Blood Pressure in Adults: Screening. 2015; [http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/high-blood-pressure-in-adults-screening?ds=1&s=Blood pressure](http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/high-blood-pressure-in-adults-screening?ds=1&s=Blood%20pressure). Accessed 06/21/16.
57. Siu AL, Force USPST. Screening for high blood pressure in adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. Nov 17 2015; 163(10):778-786. PMID 26458123
58. Coverage Determinations Manual, Part 1, Section 20.19, Ambulatory Blood Pressure Monitoring (Rev. 1, 10-03-03). Centers for Medicare and Medicaid Services 2008; http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part1.pdf. Accessed November, 2014.