



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Effective Date 8/15/2010
Next Review Date 8/15/2012
Coverage Policy Number 0406

Subject Home Sphygmomanometers

Table of Contents

Coverage Policy	1
General Background	1
Coding/Billing Information	4
References	5
Policy History	7

Hyperlink to Related Coverage Policies

Ambulatory Blood Pressure Monitoring with Automatic Portable Monitors
Cardiac Event Monitors
Home Dialysis and Associated Technologies

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

Coverage for home sphygmomanometers (i.e., blood pressure (BP) cuff and stethoscope) is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. In addition, BP cuffs and stethoscopes are specifically excluded under some benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for DME is limited to the lowest-cost alternative.

If coverage for home sphygmomanometers is available, the following conditions of coverage apply.

CIGNA covers home sphygmomanometers as medically necessary for individuals with gestational hypertension and those treated with home dialysis.

General Background

Hypertension is a risk factor for cardiovascular diseases (CVD) and kidney disease. The National Heart, Lung, and Blood Institute's (NHLBI) Joint National Committee (JNC) on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure defines hypertension as: stage one, systolic pressure of 140–159 mm Hg or diastolic pressure of 90–99 mm Hg; or stage two, systolic pressure greater than or equal to 160 mm Hg or diastolic pressure greater than or equal to 100 mm Hg. The JNC states that individuals with a mean BP of more

than 135/85 mm Hg measured at home are generally considered to be hypertensive. BP measurement is the basis for diagnosing and classifying hypertensive patients (NHLBI, 2004).

BP Measurement Methods

Noninvasive BP measurement methods include the auscultatory (i.e., mercury, aneroid and hybrid sphygmomanometers) and oscillometric methods. (Pickering, et al., 2005).

The mercury sphygmomanometer has been the gold standard for clinical measurement of BP. It is easy to read and requires no adjustment. The simplicity of the mercury sphygmomanometer design means there is negligible difference between different brands. There has been a push to replace mercury sphygmomanometers due to the mercury contamination that can occur if the device is broken (Pickering, et al., 2005).

The oscillometric technique refers to the measurement of the oscillations of pressure in a BP cuff recorded during deflation. An algorithm is used to estimate systolic and diastolic BP. No stethoscope is needed, so placement of the BP cuff is not critical. This method is less susceptible to external noise. A problem with this method is that the amplitude of the oscillation depends on the stiffness of the arteries. In older people with stiff arteries, the readings may be underestimated. The oscillometric technique is used in ambulatory BP monitors and home monitors (Pickering, et al., 2005).

Additional alternatives to the mercury sphygmomanometer are the aneroid and electronic or hybrid sphygmomanometers. Aneroid sphygmomanometers measure pressure by a mechanical system of metal bellows that expand as the cuff pressure increases and a series of levers that register the pressure on a circular scale. They are less accurate than mercury sphygmomanometers due to the instability of the system. Wall devices are more accurate than mobile devices. Electronic sphygmomanometers combine electronic and auscultatory devices. The mercury column has been replaced by an electronic gauge. A stethoscope is used in the same way as with the mercury and aneroid sphygmomanometers. The concern with aneroid and electronic devices is their accuracy. They must be regularly calibrated to avoid erroneous reading errors. Other methods of measuring BP include the finger cuff, ultrasound, and tonometry. Most of these techniques are not suitable for clinical use at this time due to their inaccuracies (Pickering, et al., 2005).

Home BP Monitoring

Auscultatory office BP measurement is the preferred setting for the diagnosis and treatment of hypertension. BP measurements in other settings include acute care, public places and home self-monitoring. The standard type of BP monitor for home use is an oscillometric device, although only a few of these devices have been properly validated through testing. Validation of the device does not mean accuracy of BP measurement by the individual. The device must be checked on each individual before the readings are considered valid. It is recommended that the accuracy of the home BP devices be evaluated every 1–2 years. Home self-monitoring requires the individual to accurately record and report BP readings. It is recommended that when readings are taken, the patient needs be resting in a comfortable chair for 3–5 minutes with the upper arm at heart level. It is recommended that three readings be taken in succession, separated by one minute, using the average as the BP reading (Pickering, et al., 2005).

The clinical applications of home sphygmomanometers are evolving as the technique becomes more widely used and scientific data are gathered. Various professional societies and organizations have general recommendations for clinical indications for self-BP monitoring, which home BP devices are used, and how the measurements should be taken. There are limited studies available with long-term health outcomes. Some of the proposed clinical indications for home BP monitoring include: detection of white-coat hypertension; guiding antihypertensive medication; the elderly, pregnancy, diabetes, resistant hypertension; improving compliance to treatment; and predicting cardiovascular outcome in hypertension. At this time, self-monitoring with home sphygmomanometers (i.e., BP cuff and stethoscope) is commonly recommended by healthcare professionals for patients with gestational hypertension and those treated with home dialysis.

U.S. Food and Drug Administration (FDA)

Non-automated sphygmomanometers require 510(k) premarket approval and are categorized as Class II devices. The FDA Compliance Policy Guide (CPG) Sec. 310.210 Blood Pressure Measurement Devices (Sphygmomanometers) Accuracy (CPG 7124.23) provides recommendations concerning accuracy and exhaust rate criteria for sphygmomanometers. The policy guide recommends that blood pressure measurement devices which do not meet accuracy and exhaust rate criteria in the American National Standards Institute (ANSI) or the

Association for the Advancement of Medical Instrumentation (AAMI) voluntary standards for non-automated, electronic and automated sphygmomanometers may, after an evaluation of all relevant facts, be recommended for legal action (FDA, 2005).

Literature Review

Agarwal and Andersen (2006) conducted a prospective cohort study of 217 veterans with chronic kidney disease (CKD) to determine the role of out-of-clinic recordings of BP in predicting end-stage renal disease (ESRD) and death. BP was measured at home and in the clinic. Patients were followed over a median of 3.5 years to assess the end points of total mortality, ESRD or the composite outcome of ESRD or death. The authors concluded that home BP monitoring provides additional prognostic information concerning ESRD and the composite end point of ESRD and death and would complement clinic BP monitoring in patients with CKD.

In a randomized controlled trial, Staeesen et al. (2004) compared the use of BP measurements taken in physician offices and at home in the treatment of patients with hypertension. Four hundred participants with a diastolic BP of 95 mm Hg, or more, as measured in the physicians' offices, were enrolled for up to one year. After a year, home BP levels were lower than office BP levels. Adjustment of antihypertensive treatment on the basis of home BP instead of office BP led to less intensive drug treatment and lower costs but also to less BP control. The authors stated their findings support a strategy for the evaluation of BP in which self-measurement and ambulatory monitoring are complementary to conventional office measurement. The authors noted there is a need for prospective outcome studies to determine the normal range of home-measured BP.

Cappuccio et al. (2004) performed a meta-analysis of 18 randomized trials to determine the effect of home BP monitoring on BP levels and the proportion of people with essential hypertension who achieved targets. For this study, 1359 individuals with essential hypertension received home BP monitoring and 1355 individuals in the control group were seen in the healthcare system. The authors concluded that for unknown reasons, BP control in people with hypertension (assessed in the clinic) and the proportion achieving targets are increased when home BP monitoring is used rather than standard BP monitoring in the healthcare system.

Professional Societies/Organizations

American Heart Association (AHA): The AHA Scientific Statement, Recommendations for BP Measurement in Humans and Experimental Animals, states the standard for home BP monitoring is an oscillometric device that records pressure from the brachial artery. The devices must be properly validated by protocols such as the AAMI and the British Hypertension Society (BHS) protocols. The accuracy of home monitoring devices must be tested at least every 1–2 years. Home monitoring of BP has not been widely accepted due to the lack of prognostic data. There is some evidence that home BP monitoring predicts morbid events and may help predict organ damage better than clinical BP measurements. Mercury sphygmomanometry is the recommended method for BP measurement in pregnancy. Self-monitoring may be useful to evaluate BP changes during pregnancy. The authors noted that “as with office BP, a lower home BP is advisable for certain patients, including diabetic patients, pregnant women, and patients with renal failure” (Pickering, et al., 2005). There has been no update to this statement since 2005.

European Society of Hypertension (ESH) and European Society of Cardiology (ESC): In 2007, the ESH and the ESC updated their 2003 recommendations for conventional, ambulatory and home BP measurement. The 2007 guidelines for the management of arterial hypertension state that when advising self-measurement of blood pressure at home: (Mancia, et al., 2007):

- Suggest the use of validated devices.
- Prefer semiautomatic devices rather than a mercury sphygmomanometer to avoid the difficulty posed by having to educate the patient on its use and the error derived from hearing problems in elderly individuals.
- Instruct the patient to make measurements in the sitting position after several minutes rest, preferably in the morning and in the evening. Inform him or her that values may differ between measurements because of spontaneous blood pressure variability.
- Avoid requesting that an excessive number of values are measured and ensure that those measurements include the period prior to drug intake so as to have information on the duration of treatment effects.

- Remember that, as for ambulatory blood pressure, normal values are lower for home than for office blood pressure. Take 130–135/85 mmHg as the values that approximately correspond to 140/90 mmHg measured in the office or clinic.
- Give the patient clear instructions on the need to provide the doctor with proper documentation of the measured values and to avoid self-alterations of the treatment regimens.

National Heart, Lung, and Blood Institute (NHLBI): The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High BP states self-measurement of BP may benefit patients by providing information on response to antihypertensive medications, therefore improving patient compliance with therapy. Self-measurement of BP can evaluate white-coat hypertension. The report states that home measurement devices need to be regularly checked for accuracy (Chobanian, et al., 2003). There has been no update to this report since 2003.

National Institutes of Health (NIH): In 2000, the NIH published the National High BP Education Program Working Group Report on High BP in Pregnancy. The report states early recognition of impending preeclampsia is based primarily on BP increases in the late second and early third trimesters. When BP starts to rise, this may be the first sign of developing preeclampsia. In selected patients, BP may be checked at home. Preeclampsia is a pregnancy-specific syndrome that usually occurs after 20 weeks of gestation. It is determined by increased BP (gestational BP elevation) accompanied by proteinuria. Gestational BP elevation is defined as BP greater than 140 mm Hg systolic or 90 mm Hg diastolic in a woman normotensive before 20 weeks. Preeclampsia always presents potential danger to mother and baby. BP of 160 mm Hg or more systolic, or 110 mm Hg or more diastolic, increases the certainty of the diagnosis of the preeclampsia syndrome and indicates the need for follow-up. Gestational hypertension refers to BP elevation that is detected for the first time after midpregnancy, without proteinuria. Gestational hypertension includes women with preeclampsia syndrome who have not manifested proteinuria, as well as women who do not have the syndrome. There has been no update to this guideline since 2000.

U.S. Preventive Services Task Force (USPSTF): The USPSTF recommendations for screening for high BP states that office BP measurements are considered the standard screening tests for high BP (USPSTF, 2007). The USPSTF does not provide recommendations for use of home sphygmomanometers.

Summary

The clinical utility of self-monitoring with home sphygmomanometers has been recognized by professional organizations and in the peer-reviewed literature for a certain subset of patients. At this time, self-monitoring with home sphygmomanometers (i.e., BP cuff and stethoscope) is commonly recommended by healthcare professionals for patients with gestational hypertension and those treated with home dialysis. Additional clinical applications of home sphygmomanometers need to be evaluated through well-designed prospective outcome studies. Additional clinical research is needed to evaluate the association between cardiovascular outcome and self-monitoring of blood pressure (BP).

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

HCPCS Codes	Description
A4660	Sphygmomanometer/blood pressure apparatus with cuff and stethoscope

ICD-9-CM Diagnosis Codes	Description
403.11	Benign hypertensive renal disease
403.91	Unspecified hypertensive renal disease
404.12-	Benign hypertensive heart and kidney disease with chronic kidney disease or

404.13	with heart failure and chronic kidney disease
404.92– 404.93	Unspecified hypertensive heart and kidney disease with chronic kidney disease or with heart failure and chronic kidney disease
584.5-586	Renal failure
642.30	Transient hypertension of pregnancy
V45.11	Renal dialysis status
V45.12	Noncompliance with renal dialysis

***Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.**

References

1. Agarwal R. Hypertension diagnosis and prognosis in chronic kidney disease with out-of-office blood pressure monitoring. *Curr Opin Nephrol Hypertens*. 2006 May;15(3):309-13.
2. Agarwal R, Andersen MJ. Prognostic importance of clinic and home blood pressure recordings in patients with chronic kidney disease. *Kidney Int*. 2006 Jan;69(2):406-11.
3. American Heart Association (AHA). Home monitoring of high blood pressure. Updated May 28, 2008 Oct 19, 2009. Accessed June 21, 2010. Available at URL address: <http://www.americanheart.org/presenter.jhtml?identifier=576>
4. Appel L, Robinson K, Guallar E. Utility of Blood Pressure Monitoring Outside of the Clinic Setting. Evidence Report/Technology Assessment No. 63 (Prepared by the Johns Hopkins Evidence-based Practice Center under Contract No. 290-97-006). Publication No. 03-004. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ). November 2002. Accessed June 21, 2010. Available at URL address: <http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat1a.chapter.799>
5. Beevers G, Lip GY, O'Brien E. ABC of hypertension. Blood pressure measurement. Part I- sphygmomanometry: factors common to all techniques. *BMJ*. 2001 Apr 21;322(7292):981-5.
6. Cappuccio FP, Kerry SM, Forbes L, Donald A. Blood pressure control by home monitoring: meta-analysis of randomised trials. *BMJ*. 2004 Jul 17;329(7458):145. Epub 2004 Jun 11.
7. Celis H, Den Hond E, Staessen JA. Self-measurement of blood pressure at home in the management of hypertension. *Clin Med Res*. 2005 Feb;3(1):19-26.
8. Centers for Medicaid and Medicare Services (CMS). Medicare benefit policy manual. Ch. 11. End Stage Renal Disease (ESRD). (Rev. 98, 12-12-08). Accessed June 21, 2010. Available at URL address: <http://www.cms.hhs.gov/manuals/Downloads/bp102c11.pdf>
9. Chobanian A, Bakris G, Cushman E, Green W, Izzo J, Jones D, Materson B, Oparil S, Wright J, Roccella J. The seventh report of the joint national committee on prevention, detection, evaluation and the treatment of high blood pressure. *JAMA*. 2003;289(19):2560-73.
10. dabl[®] Educational Trust. Classification of Sphygmomanometers . Accessed June 21, 2010. Available at URL address: <http://www.dableducational.org/index.html>
11. Feldman DM. Blood pressure monitoring during pregnancy. *Blood Press Monit*. 2001 Feb;6(1):1-7.
12. Guidance for non-automated sphygmomanometer (blood pressure cuff) guidance version 1 [guidance for industry]. Rockville, MD: United States Food and Drug Administration (FDA), Center for Devices and Radiological Health; Document Release Date: February 18, 2005. Accessed June 21, 2010. Available at URL address: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm>

13. Johnson KA, Partsch DJ, Gleason P, Makay K. Comparison of two home blood pressure monitors with a mercury sphygmomanometer in an ambulatory population. *Pharmacotherapy*. 1999 Mar;19(3):333-9.
14. Lee TH. Treatment of Hypertension. In: Libby P, Bonow RO, Mann DL, Zipes DP, editors. *Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine*. 8th ed. St Louis, MO. W.B. Saunders Co.; 2007. Ch 41.
15. Mancia G, De Backer G, Dominiczak A, Cifkova R, Fagard R, Germano G, et al. The task force for the management of arterial hypertension of the European Society of Hypertension, The task force for the management of arterial hypertension of the European Society of Cardiology. 2007 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*. 2007 Jun;28(12):1462-536. Epub 2007 Jun 11.
16. Murashima M, Cohen DL. Hypertension. In: Rakel RE, Bope ET, editors. *Conn's Current Therapy 2010*. 1st ed. St Louis, MO. W.B. Saunders, Co.; 2010. Section 5.
17. National Heart, Lung, and Blood Institute (NHLBI). Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (JNC). National Institutes of Health (NIH). NIH Publication No. 04-5230. August 2004. The Seventh Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7). Accessed June 21, 2010. Available at URL address: <http://www.nhlbi.nih.gov/guidelines/hypertension/>
18. National Institute of Health (NIH). Blood pressure. Updated May 2, 2009. Accessed June 21, 2010. Available at URL address: <http://www.nlm.nih.gov/medlineplus/ency/article/003398.htm#Definition>
19. National Institute of Health (NIH). Report of the National High Blood Pressure Education Program Working Group on High Blood Pressure in Pregnancy. *Am J Obstet Gynecol*. 2000 Jul;183(1):S1-S22.
20. O'Brien E, Waeber B, Parati G, Staessen J, Myers MG. Blood pressure measuring devices: recommendations of the European Society of Hypertension. *BMJ*. 2001 Mar 3;322(7285):531-6.
21. O'Brien E, Asmar R, Beilin L, Imai Y, Mallion JM, Mancia G,; European Society of Hypertension Working Group on Blood Pressure Monitoring. European Society of Hypertension recommendations for conventional, ambulatory and home blood pressure measurement. *J Hypertens*. 2003 May;21(5):821-48.
22. Pickering TG, Hall JE, Appel LJ, Falkner BE, Graves J, et al. Recommendations for blood pressure measurement in humans and experimental animals Part 1: blood pressure measurement in humans a statement for professionals from the subcommittee of professional and public education of the american heart association council on high blood pressure research. *Circulation* 2005;111:697-716.
23. Staessen JA, Den Hond E, Celis H, Fagard R, Keary L, Vandenhoven G, O'Brien ET; Treatment of Hypertension Based on Home or Office Blood Pressure (THOP) Trial Investigators. Antihypertensive treatment based on blood pressure measurement at home or in the physician's office: a randomized controlled trial. *JAMA*. 2004 Feb 25;291(8):955-64.
24. U.S. Preventive Services Task Force for High Blood Pressure. U.S. Preventive Services Task Force Reaffirmation Recommendation Statement. AHRQ Publication No. 08-05105-EF-2, December 2007. First published in *Ann Intern Med* 2007;147:783-6: Agency for Healthcare Research and Quality, Rockville, MD. Accessed June 21, 2010. Available at URL address: <http://www.ahrq.gov/clinic/uspstf07/hbp/hbprs.htm>
25. Williams B, Poulter NR, Brown MJ, Davis M, McInnes GT, Potter JF et al. British hypertension society guidelines for hypertension management 2004 (BHS-IV):summary. *BMJ* 2004;328:634-40.

26. Yarows SA, Julius S, Pickering TG. Home blood pressure monitoring. Arch Intern Med. 2000 May 8;160(9):1251-7.

Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	8/15/2008	0406	Home Sphygmomanometers

“CIGNA”, “CIGNA HealthCare” and the “Tree of Life” logo are registered service marks of CIGNA Intellectual Property, Inc., licensed for use by CIGNA Corporation and its operating subsidiaries. All products and services are provided by such operating subsidiaries and not by CIGNA Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, CIGNA Health and Life Insurance Company, CIGNA Behavioral Health, Inc., CIGNA Health Management, Inc., and HMO or service company subsidiaries of CIGNA Health Corporation and CIGNA Dental Health, Inc. In Arizona, HMO plans are offered by CIGNA HealthCare of Arizona, Inc. In California, HMO plans are offered by CIGNA HealthCare of California, Inc. In Connecticut, HMO plans are offered by CIGNA HealthCare of Connecticut, Inc. In North Carolina, HMO plans are offered by CIGNA HealthCare of North Carolina, Inc. In Virginia, HMO plans are offered by CIGNA HealthCare Mid-Atlantic, Inc. All other medical plans in these states are insured or administered by Connecticut General Life Insurance Company or CIGNA Health and Life Insurance Company.