



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:
Computerized Pulse Waveform Analysis

Policy #: 020
Category: Medical

Latest Review Date: February 2021
Policy Grade: **Active Policy but no
longer scheduled for regular
literature reviews and updates.**

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **Computerized Pulse Waveform Analysis (CV Profilor[®], SphygmoCor[®])** as a **non-covered** benefit and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

The CV Profilor[®]DO-2020 CardioVascular Profiling System and the SphygmoCor[®] Cardiovascular Management System are examples of non-invasive medical devices that provide an indication of arterial compliance (elasticity indices for both large and small arteries), which can be used to determine if patients have potential underlying vascular disease. The devices also measure systolic, diastolic and mean arterial pressures and pulse rate, and calculates body surface area, body mass index and pulse pressure.

These devices obtain upper-arm blood pressure values and waveform data by non-invasive methods, via the use of an oscillometric blood pressure module and via the application of specially designed equipment.

The acquisition of calibrated radial artery blood pressure waveform data involves, the coordinated use of a blood pressure cuff placed on the left upper-arm and a piezoelectric-based, direct contact, acoustical transducer placed over the right radial artery adjacent to the styloid process of the radius (by the wrist). The cuff systolic and diastolic pressures are utilized to calibrate the radial artery waveform data into units of pressure based on the median high and low value contained in a 30-second collection of blood pressure waveform data.

An embedded computer performs a “pulse contour analysis” of the calibrated, digitized blood pressure waveform data, and generates a report. The clinical data collected and analyzed are accurate and repeatable, and can be used in determining hemodynamic parameters relating to the structure, function and changes of a patient’s cardiovascular system.

The report summarizes the pulse contour analysis performed on a 30-second collection of the radial artery blood pressure waveforms. The results are based on the use of an electrical analog model which represents the vasculature as consisting of a capacitative compliance element (Large Artery Elasticity Index), an oscillatory or reflective compliance element (Small Artery Elasticity Index), an inductance and a resistance, during the diastolic decay portion of the cardiac cycle.

KEY POINTS:

A literature search was performed through February 17, 2021.

Summary

No controlled studies were found in the published literature that validates the application of non-invasive medical devices for the measuring of arterial elasticity for cardiovascular disease. No evidence was found to show that evaluation of the status of the arterial elasticity is predictive and, thus, that type of evaluation cannot be used to alter the treatment of individuals. The evidence is insufficient to demonstrate that non-invasive measurements of arterial elasticity alters patient management or improves net health outcomes.

Practice Guidelines and Position Statements

American College of Cardiology (ACC)/ American Heart Association (AHA)

In 2010, the ACC/AHA made the following recommendation:

- Measures of arterial stiffness outside of research settings are not recommended for cardiovascular risk assessment in asymptomatic adults. (Level of Evidence: C)

U.S. Preventive Services Task Force

No recommendation found specific to computerized waveform analysis.

KEY WORDS:

Hypertension, Computerized Pulse Waveform Analysis, vascular compliance, CAPWA, blood pressure waveform, arterial elasticity, CVProfilor[®], SphygmoCor[®], SCOR-Px, MaxPulse

APPROVED BY GOVERNING BODIES:

CVProfilor[®] DO-2020 CardioVascular Profiling System (Hypertension Diagnostics, Inc.) was FDA approved November 1, 2000 (K001948).

SphygmoCor[®] Cardiovascular Management System (CvMS) (AtCor Medical Pty. Ltd) was FDA approved August 31, 2007 (K070795).

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT code:

93050	Arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization and application of nonlinear mathematical transformations
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	to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, noninvasive
93799	Unlisted cardiovascular service or procedure
93922	Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries

REFERENCES:

1. American College of Cardiology Foundation and American Heart Association. 2010 Guidelines. my.americanheart.org/professional/StatementsGuidelines/ByTopic/TopicsA-C/ACCAHA-Joint-Guidelines_UCM_321694_Article.jsp.
2. Benas D, Kornelakis M, Triantafyllidi H, et al. Pulse wave analysis using the MobilOO-graph, Arteriograph and complior device: a comparative study. *Blood Press*. 2019 Apr;28(2):107-113.
3. Borlaug BA, Olson TP, Mohamed SA, et al. A randomized pilot study of aortic waveform guided therapy in chronic heart failure. *J Am Heart Assoc*. April 2014; 3(2) e000745.
4. Chirinos JA, Kips JG, Jacobs DR, et al. Arterial wave reflections and incident cardiovascular events and heart failure: the multiethnic study of atherosclerosis. *JACC*. 2012; 60(21):2170-7.
5. Cohn J.N. Vascular wall function as a risk marker for cardiovascular disease, *J of Hypertension* 1999, S41-S44.
6. CVProfilor[®]DO-2020. Technical specifications, Hypertension Diagnostics Inc. 2000
7. Zhu H, Gao Y, Cheng H, et al. Comparison of arterial stiffness indices measured by pulse wave velocity and pulse wave analysis. *Blood Press*. 2019 Jun;28(3):206-213.
8. Kampus P, Serg M, Kals J, et al. Differential effects of nebivolol and metoprolol on central aortic pressure and left ventricular wall thickness. *Hypertension*. 2011; 57:1122-1128.
9. McVeigh G.E., et al. Age-related abnormalities in arterial compliance identified by pressure pulse contour analysis; aging and arterial compliance, *Hypertension* 1999; 33:1392-1398
10. McVeigh G.E. Arterial compliance in hypertension and diabetes mellitus, *Am J Nephrol* 1996; 16:217-272.
11. Prisant L.M., Resnick L.M., Hollenberg S.M., and Jupin D. Arterial elasticity among normotensive subjects and treated and untreated hypertensive subjects. Influence of race, ethnicity and disease. *January 2002*; 12(1):63-8
12. Prisant L.M., Resnick L.M., and Hollenberg S.M. Arterial elasticity among normotensive subjects and treated and untreated hypertensive subjects. *Blood Pressure Monitoring*. October 2001; 6(5):233-7.
13. Resnick LM, et al. Pulse waveform analysis of arterial compliance: relation to other techniques, age, and metabolic variables, *AJH* 2000, 12:1243-1249.

14. Roman MJ, Devereux RB, Kizer JR, et al. High central pulse pressure is independently associated with adverse cardiovascular outcome: the strong heart study. *J Am Coll Cardiol.* 2009;54:1730-1734.
15. Sharman JE, Marwick TH, Gilroy D, et al. Randomized trial of guiding hypertension management using central aortic blood pressure compared with best-practice care. *Hypertension*, August 2015; 62:1138-1145.
16. U. S. Food and Drug Administration. (2000, November). Center for Devices and Radiological Health. 510(k) Premarket Notification Database. K001948. Retrieved June 21, 2011 from //www.accessdata.fda.gov/cdrh_docs/pdf/K001948.pdf.
17. U. S. Food and Drug Administration. (2007, August). Center for Devices and Radiological Health. 510(k) Premarket Notification Database. K070795. Retrieved June 21, 2011 from //www.accessdata.fda.gov/cdrh_docs/pdf7/K070795.pdf
18. U.S. Preventive Services Task Force. Recommendations. https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results?topic_status=All&searchterm=cardiovascular+risk.
19. Woodman RJ, Kingwell BA, Beilin LJ et al. Assessment of central and peripheral arterial stiffness: studies indicating the need to use a combination of techniques. *Am J Hypertens.* 2005 Feb;18(2 Pt 1):249-60.

POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, February 2006
Medical Policy Group, February 2007
Medical Policy Group, February 2008
Medical Policy Group, February 2009
Medical Policy Group, February 2010
Medical Policy Group, December 2010
Medical Policy Group, June 2011
Medical Policy Group, September 2012
Medical Policy Group, August 2015
Medical Policy Group, December 2015
Medical Policy Group, May 2016
Medical Policy Group, May 2018
Medical Policy Group, February 2021

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case by case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.