



BlueCross BlueShield  
of Alabama

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**Name of Policy:**

**Computerized Pulse Waveform Analysis**

Policy #: 020  
Category: Medical

Latest Review Date: May 2018  
Policy Grade: **Active Policy but no  
longer scheduled for regular  
literature reviews and updates.**

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**Background/Definitions:**

*As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.*

*The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:*

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

*Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:*

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

## **Description of Procedure or Service:**

The CV Profilor<sup>®</sup> DO-2020 CardioVascular Profiling System and the SphygmoCor<sup>®</sup> 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.

## **Policy:**

**Computerized Pulse Waveform Analysis (CV Profilor<sup>®</sup>, SphygmoCor<sup>®</sup>) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational**.**

*Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate 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.*

## **Key Points:**

Blood pressure is the most frequently measured property of peripheral vasculature. However, compliance reflecting the change in vascular dimensions relative to the pulse pressure may be a more subtle index of vascular dysfunction associated with aging and diseases such as hypertension, diabetes mellitus, coronary heart disease or congestive heart failure. The development of computerized pulse waveform analysis (CAPWA) has simplified the acquisition and analysis of data, and has made these measurements accessible in an outpatient setting.

Previous studies indicate that patients with documented vascular disease or with a history of vascular events tend to have less compliant arteries than patients with documented vascular disease. Patients with a history of vascular events also tend to have less compliant arteries than control subjects. In addition, multiple risk factors for the future development of vascular disease may also be associated with a less compliant arterial circulation. Therefore, a reduced arterial compliance may provide an index of early arterial damage that could predispose patients to the development of major vascular disease.

In 2005, Woodman et al evaluated several techniques for measuring arterial stiffness and compared them with central pulse wave velocity (PWV). A total of 30 men participated in the study, 15 with coronary artery disease and 15 healthy men. Measures performed included central and distal pulse wave velocity, large and small artery compliance (C1 and C2, respectively), and stroke volume/pulse pressure (SV/PP), augmentation index (Aix) and central pulse pressure (CPR) (Sphygmocor), stiffness index (SI), systemic arterial compliance (SAC), and brachial PP. The authors concluded that large and small artery compliance, and stroke volume/pulse pressure, and systemic arterial compliance show poor agreement with central pulse wave velocity, an established measure of central arterial stiffness.

## **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)

## **Key Words:**

Hypertension, Computerized Pulse Waveform Analysis, vascular compliance, CAPWA, blood pressure waveform, arterial elasticity, CVProfilor<sup>®</sup>, SphygmoCor<sup>®</sup>, SCOR-Px

**Approved by Governing Bodies:**

CVProfilor<sup>®</sup> DO-2020 CardioVascular Profiling System (Hypertension Diagnostics, Inc.) was FDA approved November 1, 2000 (K001948).

SphygmoCor<sup>®</sup> 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.

ITS: Home Policy provisions apply

FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity

**Current Coding:**

CPT code:

<b>93050</b>	Arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization and application of nonlinear mathematical transformations to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, noninvasive <b>(Effective 01/01/2016)</b>
<b>93799</b>	Unlisted cardiovascular service or procedure
<b>93922</b>	Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries

**Previous Coding:**

CPT code:

<b>0311T</b>	Non-invasive calculation and analysis of central arterial pressure waveforms with interpretation and report <b>(Deleted effective 01/01/2016)</b>
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**References:**

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### **Policy History:**

Medical Policy Group, September 2001  
 Medical Review Committee, September 2001  
 Medical Policy Administration Committee, October 2001  
 Medical Policy Group, February 2004  
 Medical Policy Group, February 2006 (1)  
 Medical Policy Group, February 2007 (1)  
 Medical Policy Group, February 2008 (1)  
 Medical Policy Group, February 2009 (1)

Medical Policy Group, February 2010 **(1)** No changes

Medical Policy Group, December 2010; 2011 Coding update

Medical Policy Group, June 2011, **(1)** Update to Description, Policy, Key Points, Key Words, Approved by Governing Bodies and References related to addition of SphygmoCor<sup>®</sup> device; also removed code 93922, as this is not an appropriate code for usage.

Medical Policy Administration Committee, July 2011

Medical Policy Group, September 2012 **(3)**: **Active Policy but no longer scheduled for regular literature reviews and updates.**

Medical Policy Group, August 2015 **(4)**: Updates to Key Points and References. No change to policy statement. Policy remains active, but not scheduled for regular literature reviews and updates.

Medical Policy Group, November 2015: 2016 Annual Coding Update. Added new CPT code 93050 to the current coding section. Also added existing CPT code 93922 to policy. Created Previous coding section and added deleted code 0311T.

Medical Policy Group, May 2016 **(4)**: Updates to Key Points, Key Words, and References. No change to policy statement.

Medical Policy Group, May 2018 **(4)**: Updates to Key Points and References. No change to policy statement.

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*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.*