Name of Policy:
Computerized Pulse Waveform Analysis

Policy #: 020
Category: Medical

Latest Review Date: September 2012
Policy Grade: Active Policy but no longer scheduled for regular literature reviews and updates.

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®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.

Policy:
Computerized Pulse Waveform Analysis (CV Profilor®, SphygmoCor®) 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
members' 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 vasculary 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.

No controlled studies were found in the published literature that validate the application of non-invasive medical devices for the measuring of arterial elasticity for cardiovascular disease or that provide comparisons to other non-invasive techniques. 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.

**February 2007 Update**

No new published peer-reviewed literature was found that would alter the coverage statement on this policy.

**February 2008 Update**

No new published peer-reviewed literature was found that would alter the coverage statement on this policy.

**February 2009 Update**

No new published peer-reviewed literature was found that would alter the coverage statement on this policy.

**February 2010 Update**

A literature search via Medline and PubMed did not identify any new studies that would alter the coverage statement of this policy.

**June 2011 Update**

No new published peer-reviewed literature was found that would alter the coverage statement on this policy.

**Key Words:**

Hypertension, Computerized Pulse Waveform Analysis, vascular compliance, CAPWA, blood pressure waveform, arterial elasticity, CVProfilor®, SphygmoCor®
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.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity
Pre-certification/Pre-determination requirements: Not applicable

Current Coding:
CPT code: 93799 Unlisted cardiovascular service or procedure

References:
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® 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.

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.