



## Clinical Review Criteria

### Plethysmography

- Lower Limb Deep Vein Thrombosis (DVT)
- Occlusive Peripheral Arterial Disease (PAD)

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## Criteria

### For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	<a href="#">Plethysmography (20.14)</a>
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

### For Non-Medicare Members

Clinical review is no longer required for this service.

### PADnet System for the Detection of Peripheral Vascular Disease

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

## Background

Plethysmography (PG) is a noninvasive method used to measure changes in blood flow or air volume within an organ or the whole body. The term plethysmography is a combination of the ancient Greek words plethysmos, which means increase, and grapho which means write (Alnaeb 2007). Total body plethysmography measures intrathoracic gas volume and volume change, pulmonary plethysmography measures the volume of air that can be voluntarily inhaled or exhaled, limb plethysmography measures changes in the volume of a limb in response to change in blood volume, and genital plethysmography measures blood flow in the genitals.

There are several types of plethysmographic systems that measure blood flow and velocity in the carotid artery and peripheral vascular system. These include electrical impedance plethysmography, segmental plethysmography, oculoplethysmography, strain gauge plethysmography, photoelectric plethysmography, air plethysmography, and several others. These instruments indirectly detect and quantify vascular disease based in alterations in pulse wave contour, blood pressure, or arterial or venous blood flow (Barnes 1991, Graham 1996).

Oculoplethysmography indirectly measures the hemodynamic significance of internal carotid artery stenosis or occlusion by demonstration of an ipsilateral delay in the arrival of ocular pressure transmitted from branches of the ophthalmic artery. It detects only severe narrowing or blockage and is incapable of directly measuring the flow or demonstrating anatomic information or quantifying percent of stenosis. Other tests (ultrasound or angiography) are required to confirm the diagnosis and have largely replaced this technique (Graham 1996).

Photoplethysmography (PPG) is a technique based on the determination of optical properties of the underlying tissue. It uses an optical light-emitting diode in a sensor that is attached to the skin and transmits light through the dermis into the subcutaneous tissue. A photoelectric cell captures the reflected light to detect changes in blood volume. Changes in the beam wavelength are measured by a microcomputer and a plethysmogram representing the blood flow of the limb is produced. PPG is not strictly a plethysmographic technique as its operation is based on the principles of light densitometry and photon diffusion theory. Both PPG and light reflection rheography (also known as quantitative PPG), have been used in the detection of varicose veins, venous insufficiency, phlebothrombosis, and other peripheral venous disease (Higgins 1986, Keechi 2008, Khandanpour 2009).

Strain-gauge plethysmography (SPG) uses the technique of filling the distal veins of the lower limbs by inflation of a tourniquet around the thigh, causing occlusion of the veins, then indirectly measuring the changes in venous outflow and capacitance in response to release of tourniquet by a strain gauge placed around the calf. The strain-gauge plethysmography may also be used to assess the effectiveness of different types of compression devices on the legs of patients with venous deficiency (Siau 2010).

Impedance plethysmography is performed by placing two sets of electrodes around the patient's calf and an oversized blood pressure cuff around the thigh. The electrodes sense a change in blood volume and record it on a strip chart. Changes in venous filling are produced by inflating the thigh cuff to obstruct venous return, then deflating the cuff to re-establish blood flow. The time required for the venous volume in the calf to return to baseline is recorded. A clot in the popliteal or proximal veins will delay venous emptying. In water plethysmography, an extremity is enclosed in a water-filled chamber where volume changes can be detected. Air plethysmography is based on the same principle but uses an air-filled long cuff. As indicated these techniques depend on detecting alterations in venous outflow and capacitance in the presence of thrombi in the deep veins. Extrinsic compression of the proximal veins by pregnancy tumor, or poor venous outflow in cases of severe edema, all may lead to false positive results. It was also reported that plethysmographic techniques are inaccurate in detecting deep vein thrombosis in vessels in which the venous outflow has not been significantly impeded by the thrombus (Graham 1996, Locker 2006, Mosti 2010).

Segmental plethysmography (or pulse volume recording [PVR]) is a noninvasive hemodynamic measurement that can potentially provide an initial assessment of the location and severity of peripheral arterial disease. Segmental limb plethysmography waveform analysis is based on evaluation of waveform shape and signal amplitude. Standardized criteria relating waveform changes to anatomic site and hemodynamic severity of disease are used in the diagnostic interpretation. The test involves placing cuffs around the leg at selected locations and connecting them to a plethysmograph to detect and graphically record changes in limb volume. Normally, a single, large thigh cuff is used along with regular-sized calf and ankle cuffs, plus a brachial cuff that reflects the undampened cardiac contribution to arterial pulsatility. Once the cuff is inflated to 60–65 mmHg (a pressure sufficient to detect volume changes without resulting in arterial occlusion), pulse volume recordings are obtained. These PVRs have the potential of detecting and localizing significant occlusive lesions. The tests can also be repeated over time to follow disease progression. Segmental plethysmography is an indirect examination of the artery and may not detect multiple stenoses located at or above the level of the cuff (Gerhard-Herman 2006, Clements, TASC).

Plethysmography have the potential of providing rapid and non-invasive diagnosis of deep vein thrombosis, and peripheral arterial diseases, and was once considered to be the primary diagnostic test for noninvasive detection of deep vein thrombosis (Stevens 2007, Abbara 2010). However, it has been reported that due to its inaccuracy and with the improvements in both direct real-time ultrasonic imaging and Doppler ultrasonic flow detection and color-flow mapping, plethysmography as well as other indirect techniques are assuming a less important role in vascular diagnosis (Barnes 1991, Stevens 2007).

Several plethysmographic devices have received FDA clearance as Class II medical devices to assist in the diagnosis of vascular disease. PADnet System for the detection of peripheral vascular disease was previously reviewed by MTAC in 2005 and did not meet its evaluation criteria due to lack of evidence on the system. The current review focuses on the use of plethysmography in the diagnosis of deep vein thrombosis and occlusive peripheral arterial disease.

The PADnet lab, manufactured by BioMedix, is a noninvasive cardiovascular blood flow monitor intended for use by trained medical professionals for the early detection of peripheral vascular disease (FDA Home page). The manufacturer claims that it detects blockages in arteries and the quality of blood flow using pulse volume recording and oscillometer segmental blood pressure measurement. It is used with a pressure cuff that is applied

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and inflated to shut off the flow in the artery. When deflated the device records the oscillations and assigns a systolic pressure value and the results sent to the vascular specialists (BioMedix Web site). The device includes a laptop computer and a color printer on a medical grade car.

The FDA cleared PADnet for marketing in October 2004 based on its equivalence to legally marketed predicate devices.

## Medical Technology Assessment Committee (MTAC)

### **PADnet system**

#### **08/01/2005: MTAC REVIEW**

**Evidence Conclusion:** There is no published data to date on the PADnet system other than the marketing information provided by BioMedix, the manufacturer of the device, on their web site.

**Articles:** The search did not reveal any studies or articles on the PADnet system.

The use of PADnet system in the evaluation for early detection of peripheral vascular disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

### **PADnet system**

#### **06/20/2011: MTAC REVIEW**

**Evidence Conclusion:** Use of plethysmography for detecting deep vein thrombosis. The published studies showed variable accuracies for the different plethysmographic techniques. The sensitivity ranged from 20-100% and specificity from the lower 60s to the upper 90s. The negative predictive value was as high as 100% for some systems such as digital photoplethysmography (D-PPG) used for screening asymptomatic patients at high risk for developing DVT. It performed better for proximal vs. distal (calf) DVTs. In a meta-analysis of 78 studies, Locker and colleagues (Evidence table 1) evaluated the performance of plethysmography and rheography in the diagnosis of DVT. Sensitivity and specificity were 75% and 90% respectively for impedance plethysmography, 83% and 81% for strain-gauge plethysmography, 85% and 91% for air plethysmography, and 91% and 71% for light-reflex rheography. The authors concluded that the accuracy of these techniques is insufficient to use them as stand-alone tests for screening for DVT. Siau and colleagues, 2010 (Evidence table 2) examined the accuracy of Well's clinical predictive tool, D-dimer analysis, and computerized strain-gauge plethysmography (CSGP) in the assessment of patients with suspected DVT, using imaging as a gold standard. The results showed that CSPG had a poor sensitivity and relatively low negative predictive value. CSPG performed better for above knee DVT vs. calf DVT, but still had an insufficient accuracy. Its use with D-Dimer did not add value to D-Dimer testing alone.

Williams and colleagues (2005) also assessed the clinical utility of D-Dimer, strain-gauge plethysmography and a combination of both in the diagnosis of DVT in 243 patients with low, moderate, and high clinical pretest probability (PTP) of DVT. A definitive diagnosis of the disease was made based on a compression ultrasound. The results of the study showed that the plethysmography had lower negative predictive values than those of D-dimer test for patients with low, moderate, or high PTP. The addition of strain-gauge plethysmography did not improve clinical decision making in any of the groups. Sharif-Kashani, et al (Evidence table 3) evaluated the role of digital photoplethysmography (D-PPG) in screening asymptomatic patients at high risk for developing DVT. They examined 337 lower limbs of 169 patients and showed that D-PPG had 100% sensitivity in detecting DVT in these patients at high risk. It also had a 100% negative predictive value, i.e. it is a good test for excluding the disease. However, it had a lower specificity indicating that patients with abnormal results will need further investigations. It is to be noted that all detected DVTs were proximal and the results cannot be generalized to distal vein thrombosis. There is insufficient published evidence evaluate the accuracy of plethysmography in the diagnosis of clinically suspected upper extremity DVT. Use of plethysmography for detecting occlusive peripheral artery disease (PAD). The majority of published studies on the use plethysmography for detecting lower limb peripheral occlusive disease examined the accuracy and predictive values of photoplethysmography (PPG) and/or agreement with other standard measures of ankle brachial pressure index (ABPI). In a study of selected 131 patients diagnosed with PAD, Khandanpour and colleagues, 2009 (Evidence table 4) found a significant agreement between ankle brachial pressure index (ABPI) derived from photoplethysmography (PPG) or continuous wave Doppler (CW-Doppler). Allen et al, 2008 (Evidence table 5) assessed the diagnostic accuracy of novel bilateral photoplethysmography toe pulse measurement techniques for the detection of significant lower limb PAD. The study included 111 subjects of whom 48 (43%) had a significant disease. The study results show high accuracy and significant agreement between bilateral PPG and ankle-brachial pressure index in detecting higher grade peripheral artery disease in the lower limbs. With the pulse measurement techniques studied PPG was found to have high negative predictive value when used to screen population with low prevalence of the

disease, and a high positive predictive value among high disease prevalence patients referred to a vascular laboratory.

Other published small studies evaluated different algorithms and devices based on PPG for the assessment of PAD and concluded that the technology may be used as a noninvasive screening tool for early detection of the disease. It was reported however, that the technology may not provide valid measurements for patients with very high systolic arterial pressure, obesity, edema, or those with stiff arteries e.g. in diabetes mellitus, hypercholesterolemia, end-stage renal disease, and advanced age (Alnaeb 2007). The effect of using plethysmography vs. other standard techniques on clinical decision making and outcome of patients diagnosed with early or significant peripheral artery disease was not studied.

**Articles:** The following studies were selected for critical appraisal based on their population sizes and methodological quality: Allen J, Overbeck K, Nath AF, et al. A prospective comparison of bilateral photoplethysmography versus the ankle-brachial pressure index for detecting and quantifying lower limb peripheral arterial disease. *J Vasc Surg.* 2008; 47:794-802. See [Evidence Table](#). Khandanpour N, Armon MP, Jennings B, et al. Photoplethysmography, an easy and accurate method for measuring ankle brachial pressure index: can photoplethysmography replace Doppler? *Vasc Endovascular Surg.* 2009; 43:578-582. See [Evidence Table](#). Locker T, Goodacre S, Sampson F, et al. Meta-analysis of plethysmography and rheography in the diagnosis of deep vein thrombosis. *Emerg Med J* 2006; 23:630-635. See [Evidence Table](#). Sharif-Kashani B, Behzadnia N, Shahabi P, et al. Screening for deep vein thrombosis in asymptomatic high-risk patients: a comparison between digital photoplethysmography and venous ultrasonography. *Angiology.* 2009; 60:301-317. See [Evidence Table](#). Siau K, Davies A, and Laversuch. Is there still a role for computerized strain gauge plethysmography in the assessment of patients with suspected deep vein thrombosis? *Q J Med* 2010; 103:259-264. See [Evidence Table](#).

The use of plethysmography in the evaluation of lower limb deep vein thrombosis (DVT) and occlusive peripheral arterial disease (PAD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## Applicable Codes

**Medicare – Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

**Non-Medicare – medical necessity review no longer required**

CPT® or HCPC Codes	Description
93050	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, non-invasive
93922	Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries, (eg, for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus bidirectional, Doppler waveform recording and analysis at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus volume plethysmography at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries with, transcutaneous oxygen tension measurement at 1-2 levels)
93923	Complete bilateral noninvasive physiologic studies of upper or lower extremity arteries, 3 or more levels (eg, for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental blood pressure measurements with bidirectional Doppler waveform recording and analysis, at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental volume plethysmography at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental transcutaneous oxygen tension measurements at 3 or more levels), or single level study with provocative functional maneuvers (eg, measurements with postural provocative tests, or measurements with reactive hyperemia)
93924	Noninvasive physiologic studies of lower extremity arteries, at rest and following treadmill stress testing, (ie, bidirectional Doppler waveform or volume plethysmography recording and analysis at rest with ankle/brachial indices immediately after and at timed intervals following performance of a standardized protocol on a motorized treadmill plus recording of time of onset of claudication or other symptoms, maximal walking time, and time to recovery) complete bilateral study

**\*Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

\*\*To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
08/01/2005	08/01/2005 <sup>MDCRPC</sup> , 07/05/2011 <sup>MDCRPC</sup> , 05/01/2012 <sup>MDCRPC</sup> , 03/05/2013 <sup>MDCRPC</sup> , 01/07/2014 <sup>MPC</sup> , 11/04/2014 <sup>MPC</sup> , 09/01/2015 <sup>MPC</sup> , 07/05/2016 <sup>MPC</sup> , 05/02/2017 <sup>MPC</sup> , 03/06/2018 <sup>MPC</sup> , 03/05/2019 <sup>MPC</sup> , 03/03/2020 <sup>MPC</sup> , 03/02/2021 <sup>MPC</sup> , 03/01/2022 <sup>MPC</sup> , 03/07/2023 <sup>MPC</sup>	08/02/2016

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee

<sup>MPC</sup> Medical Policy Committee

Revision History	Description
08/02/2016	Approved to stop clinical review for non-medicare members