KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Ankle Brachial Index Device

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Ankle Brachial Index Device***, for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

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.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

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

Peripheral artery diseases (PAD) are atherosclerotic diseases resulting in occlusion of peripheral arteries (abdominal aorta, iliac, and lower extremity arteries). The prevalence of lower extremity PAD, around the globe, is estimated at 3 to 12% (Hirsch et al., 2006; Norgren et al., 2007; Olin & Sealove, 2010). Patients may experience rest pain, ulceration, claudication, hospitalizations, and even amputation of limb. PAD may also be asymptomatic. The rate of myocardial infarction, stroke, and cardiovascular mortality is significantly increased with PAD (Olin & Sealove, 2010).

Several risk factors have been identified. However, The American College of Cardiology/American Heart Association (ACC/AHA) guidelines on PAD have recognized specific risk groups with a higher prevalence of PAD. These include age ≥ 70 years, age 50 to 69 years with a history of diabetes or smoking, age 40 to 49 with diabetes and at least one other risk factor for atherosclerosis, leg symptoms indicative of claudication with

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exertion or ischemic pain at rest, abnormal lower extremity pulse examination, known atherosclerosis at other sites (coronary, carotid, renal artery disease) (Hirsch et al., 2006).

Ankle-brachial-index (ABI) using doppler is one of the tests used to diagnose peripheral artery disease (PAD). It measures the ratio of the systolic ankle to brachial pressure. PAD is defined by an ABI ≤ 0.9. However, studies have reported a low utilization of the ABI due to lack of skills to perform the procedure (Mohler et al., 2004). ABI is also incorrectly used in primary care (Davies, Kenkre, & Williams, 2014; Nicolai et al., 2009). In addition, the procedure is time consuming and this might contribute to its low use in busy healthcare centers (Davies et al., 2014; Nicolai et al., 2009). These limitations result in underdiagnosis and undertreatment of PAD.

Several automated ABI devices have been developed to overcome the limitations of Doppler ABI. These encompass devices using oscillometric technology and plethysmographic-based technology. Oscillometric-based devices seem to be less accurate (Verberk, Kollias, & Stergiou, 2012) in computing ABI.

The plethysmographic method is based on reperfusion plethysmography. “A dual-chamber cuff applied to each limb consists of an upper occlusion chamber and a lower detection chamber. When the pressure of the upper occlusion chamber has exceeded arterial systolic pressure, the distal detection chamber detects a gradual decrease in limb volume as a result of blood redistribution in the absence of arterial blood inflow. As the pressure in the occlusion chamber is then incrementally reduced and reaches systolic pressure, arterial blood flow to the limb is restored, which is detected as a volume increase in the lower chamber. The pressure in the upper occlusion chamber at the point when this lower chamber volume increase occurs, is taken as the limb arterial systolic pressure” (Davies & Williams, 2016).

Several manufacturers have developed automated ABI machines using plethysmography technology. Manufactured by Huntleigh Diagnostics, Cardiff, UK, the Dopplex Ability is an automated device that measures ankle-brachial index (ABI) and pulse volume recordings (PVR). It uses air plethysmography technology to perform these assessments (Millen et al., 2018). The Dopplex ability provides fast and easy measurements with a printout of results from integrated software package. ABI’s are computed in three minutes (without the need to rest the patient), interpreted and displayed with pulse volume waveforms on LCD panel. The Dopplex ability system includes Dopplex ability automatic machine, one box of disposable sleeves, four pieces set of standard 8½"-14"cuffs, one pack of standard thermal paper, and one set of adhesive paper. The Dopplex ability is intended for wound care for arterial disease before deciding on compression bandaging. It is also considered for PAD detection, and congestive heart disease screening (identification of risk factors) (https://www.usamedicalsurgical.com/huntleigh-dopplex-ability-automatic-abi-system/). Other manufacturers include Newman Medical (USA), Enverdis, Skidmore Medical.

Medical Technology Assessment Committee (MTAC)

Ankle-Brachial Index device using plethysmographic method for the diagnosis of peripheral artery disease
04/08/2019: MTAC REVIEW

Evidence Conclusion:

Low evidence suggests that automated ABI device using plethysmographic method (Dopplex Ability) shows:

- moderate agreement with doppler manual method and low reliability
- moderate sensitivity along with high specificity and accuracy for detection of PAD in comparison with the Doppler method as a gold standard
- a conflicting proportion of failing measurements

More studies are needed to clarify whether Dopplex Ability alone can provide enough diagnostic accuracy

Articles: PubMed was searched through March 15, 2019. Search terms include ((ABI automated system OR Dopplex Ability)) AND (peripheral artery disease OR PAD). Other terms consist of Automated plethysmography AND ankle-brachial index AND doppler ultrasound. SimpleABI system OR simpleABI automated system OR ABI Doppler system OR ABI automated system was searched. Google scholar was also searched. The search was limited to English language publications and human populations. RCTs and observational studies were included as filter in the search. The reference lists of relevant studies were reviewed to identify additional publications. See Evidence Table**.**

The use of Ankle-Brachial Index device using plethysmographic method for the diagnosis of peripheral artery disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No Specific Codes	

***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.

Date Created	Date Reviewed	Date Last Revised
05/07/2019	05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC, 05/03/2022MPC, 05/02/2023MPC, 03/12/2024MPC, 03/04/2025MPC	05/07/2019

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
05/07/2019	MPC approved to adopt a non-coverage policy for Ankle Brachial Index Device

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