

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Diagnostics Assessment Programme

### Automated ankle brachial pressure index measurement devices for assessing peripheral arterial disease in people with leg ulceration

#### Final scope

April 2022

#### **1 Introduction**

The National Wound Care Strategy Programme and the Department for Health and Social Care identified using automated ankle brachial pressure index measurement devices for people with leg ulcers as an area that would benefit from NICE guidance. On the basis of a topic briefing, the topic selection oversight panel selected and routed the topic for guidance development by the Diagnostics Assessment Programme.

The final scope was informed by discussions at the scoping workshop on 8 March 2022 and the assessment subgroup meeting held 23 March 2022. A glossary of terms and a list of abbreviations are provided in appendices A and B.

#### **2 Description of the technologies**

This section describes the properties of the diagnostic technologies based on information provided to NICE by manufacturers and experts, and information available in the public domain. NICE has not carried out an independent evaluation of this description.

##### **2.1 Purpose of the medical technologies**

Leg ulcers are leg wounds that are slow to heal and usually develop on the inside of the leg, just above the ankle. When the leg ulcer is caused by a problem in the blood flow in the veins the treatment involves using compression, such as bandages or stockings. But strong compression therapy can disturb the arterial blood supply in the leg and so should not be offered to people with peripheral arterial disease.

To help diagnose peripheral arterial disease, and identify people who should not have compression therapy, the ankle brachial pressure index (ABPI, also called ankle brachial index or ABI) is measured. Currently, this is done using a hand-held doppler ultrasound probe and a manually inflated blood pressure cuff to measure systolic pressures of the arteries in each limb (sphygmomanometer) and the ABPI is calculated manually (see section 3.3.2 for the steps in the test).

Measuring the ABPI this way is time-consuming and can take up to an hour to complete. Arteries need to be located and systolic pressure measurements taken on each limb 1 at a time, with multiple measurements taken on each ankle. Because the test uses measures of systolic pressure, a doppler probe is used to determine when blood is flowing and consequently when the reading should be taken from the sphygmomanometer. When the doppler probe is placed on an artery the sound of the blood flowing through the artery can be heard. This sound disappears when a blood pressure cuff is inflated and tightens around the artery. When the cuff is deflated, the point at which the blood starts to flow again and the sound from the doppler returns is the point at which the blood pressure for ABPI calculation (systolic blood pressure) is recorded from the sphygmomanometer. The healthcare professional doing the test needs to have expertise in using the doppler probe and doing the test. More experienced testers may also listen to the sound from the doppler for its waveform pattern (monophasic, biphasic, triphasic) in the ankles. This can provide information about the quality of arterial circulation.

The test is often uncomfortable for people with leg ulcers. Lying down both for resting before the test and during the test is needed and this is often difficult for people with leg ulcers who may also have difficulties with mobility in general (because of the ulcers or other conditions such as hip or back problems that are more common in older age). Placing blood pressure cuffs and inflating them near an ulcer can be painful.

Using automated ABPI measurement devices could help make measuring ABPI more convenient for people with leg ulcers and free up staff time. They could reduce the time needed to rest before a test and the time to do the test and get the ABPI result and even the need to lie down during the test. They could reduce the number of times blood pressure cuffs need to be inflated in the ankles or fully remove the need to use cuffs in the ankles, depending on the technology used. Any improvement in the accuracy of detecting peripheral arterial disease could reduce time to treatment, leading to improved outcomes for people with leg ulcers. Information on arterial circulation measured by some of the automated tests can also be stored, allowing later review

potentially by a more experienced clinician. Experts highlighted that this is not possible with all manual doppler systems.

## **2.2 Product properties**

The technologies in this section are included in the assessment because they automatically do the ABPI test (in terms of taking measurements and calculating ABPI).

These technologies use different methods to detect blood flow. The doppler based device in section 2.2.1 uses doppler waveform signals, oscillometry based devices assess oscillations in the vessel wall and plethysmography-based devices assess blood volume changes. The signal measured by these methods is either directly used to estimate blood pressure or assists the measurement of this with a pressure cuff.

The automated ABPI measurement technologies that do not use a doppler probe cannot provide doppler waveforms as an output. But some provide an alternative output that aims to provide information about the quality of arterial circulation in the ankles. Clinical experts highlighted that it is uncertain if the information provided by these outputs is equivalent to doppler waveforms and noted that this information can be important to consider when making decisions about care (see section 3.3.2). Further training may also be needed to interpret these outputs.

Technologies will only be included in guidance if they are available to the NHS and have appropriate regulatory approval.

### **Doppler-based devices**

#### *2.2.1 BlueDop Vascular Expert (BlueDop Medical)*

BlueDop Vascular Expert is a wireless medical device that can be used to measure ABPI. The BlueDop kit contains a hand-held device with a doppler probe (BlueDop egg), a charging base and a tablet computer pre-loaded with BlueDop software. Blood pressure in the arms is measured independently of the BlueDop equipment and is entered manually into the software. Ankle pressure measurements are done without cuffs using the BlueDop egg device. This is placed on the ankles 1 at a time. The BlueDop egg is able to communicate using Bluetooth with the software which analyses the doppler signal and converts this to a pressure measurement. The software automatically calculates ABPI as a ratio of mean ankle and arm blood pressure (rather than ratio of systolic blood pressures). Its maximum value is 1.0. ABPI values between 1.0 and 0.8 are considered normal and values between 0.79 and 0.50 are consistent with claudication (a potential symptom

of peripheral arterial disease, see section 3.1) and values between 0.49 and 0.0 are consistent with critical limb ischaemia (also called chronic limb-threatening ischaemia, see section 3.1).

In addition to ABPI, BlueDop Vascular Expert provides both visual and sound evidence of doppler waveforms and can indicate if the waveform is monophasic or multiphasic (tri- or biphasic). Additionally the system provides information on perfusion pressure (mean pressure) and vascular reserve.

Measuring the ankle blood pressures and calculating the ABPI takes less than 1 minute. All the measurements during the test can be taken in a seated position and there is no need to rest beforehand. The device provides the doppler waveforms both as a sound and a graph. The manufacturer states that BlueDop Vascular Expert is of particular value when using a blood pressure cuff is challenging because of for example hardening of blood vessels (arterial calcification), swelling of the leg, extensive ulceration and wound dressings or difficulty in lying flat.

## **Oscillometric devices**

### *2.2.2 boso ABI-system 100 (BOSCH + SOHN)*

boso ABI-system 100 is a CE-marked medical device that uses an oscillometric method. The device is connected to 4 blood pressure cuffs and comes with a USB cable to connect it to a computer. The kit also includes software that is needed to analyse and view the results that needs to be installed on a computer (not supplied as part of the kit). Patients should rest for about 5 minutes before the test and lie still during the test which takes 1 minute. The cuffs inflate and deflate automatically and the blood pressure measurements are simultaneous. ABPI is calculated automatically.

In addition to ABPI, the boso ABI-system 100 provides information on inter-arm difference in blood pressure, oscillation profile and pulse wave velocity.

The device is suitable for people whose upper arm circumferences are between 22 cm and 48 cm and ankle circumferences are between 18 cm and 38 cm. The test should not be used for people with severe heart failure. Cuffs should not be placed over open wounds, implanted stents or lymphoedema.

### *2.2.3 WatchBP Office ABI (Microlife)*

WatchBP Office ABI is a CE-marked (class 2a) portable medical device that uses an oscillometric method. The device has a screen to view the results and it is connected to 2 blood pressure cuffs at a time. The cuffs inflate and deflate automatically. The manufacturer recommends that the patient lies still for at

least 5 minutes before starting the measurement process. They also need to lie down and remain still during the test which takes 4 minutes. The blood pressure is first measured simultaneously in both arms and then in each leg, one at a time, whilst simultaneously re-measuring it in the arm that had the highest pressure. ABPI is calculated automatically.

In addition to ABPI, the WatchBP Office ABI provides information on atrial fibrillation, hypertension and inter-arm difference in blood pressure.

The device can be connected to a computer and used with WatchBP software. The device can be used in adults and children aged 3 years or older. The device should not be used when using blood pressure cuffs is not suitable (for example in people with arm and leg stents).

#### *2.2.4 WatchBP Office Vascular (Microlife)*

The WatchBP Office Vascular uses the same hardware and software as the WatchBP Office ABI for the assessment of ABPI. Indications for use are the same as this device (see section 2.2.3). However, it has additional functionality to measure pulse wave velocity.

### **Oscillometry and plethysmography-based devices**

#### *2.2.5 MESI ABPI MD (MESI)*

MESI ABPI MD is a CE-marked (class 2a) portable wireless medical device that uses oscillometry and plethysmography. The device has a screen to view the results and it is connected to 3 blood pressure cuffs. No rest is needed before the test, but the person needs to be lying down and still during the test. The cuffs are put on 1 arm and each ankle. The cuffs inflate and deflate automatically and blood pressure measurement is simultaneous. ABPI is automatically calculated by the software within the device in 1 minute. The company recommend using cuffs on each arm if a difference in arm blood pressure is suspected. The company state that ABPI between 0.9 and 1.4, as measured by this device, should be considered normal and values below and above this range suggest referral for further investigation would be warranted. This range may be slightly higher than what is typically used in current practice with manual doppler (see section 3.3.2). MESI ABPI MD can be connected to a computer to store the results or to get a printout of the ABPI result with MESIresults software.

When used connected to a computer with the necessary software, in addition to ABPI, MESI ABPI MD also displays pulse waveforms and oscillation profile. The manufacturer states that these provide a visual representation of the state

of the person's blood flow in their lower extremities and are an aid to take a decision about whether or not this person requires further vascular examination. They further state that combining both the ABPI result and pulse waveform represents best practice in evaluating the presence and severity of peripheral arterial disease.

MESI ABPI MD is intended for use in people aged 10 years and over.

#### *2.2.6 MESI mTABLET ABI (MESI)*

MESI mTABLET ABI is a CE-marked (class 2a) portable wireless medical device that uses oscillometry and plethysmography. It consists of a medical tablet computer and 4 blood pressure cuffs that are connected to the tablet. The manufacturer recommends that the patient lies still for at least 5 minutes before starting the measurement process. They also need to lie down and remain still during the test. The cuffs inflate and deflate automatically. The blood pressure is first measured simultaneously in both arms and then in both ankles together with re-measuring it in the arm that had the highest pressure. ABPI is automatically calculated by software within the device. The company state that ABPI between 0.9 and 1.4, as measured by this device, should be considered normal and values below and above this range suggest referral for further investigation would be warranted (see section 3.3.2 for typical interpretation of ABPI values when manual doppler is used).

In addition to ABPI, MESI mTABLET ABI displays pulse waveforms and oscillation profile (please see 2.2.5 for intended use).

The test should not be used in people aged 10 years and under. The device can be integrated with electronic health records systems.

### **Plethysmography-based devices**

#### *2.2.7 Dopplex Ability Automatic ABI System (Huntleigh Healthcare)*

Dopplex Ability Automatic ABI System is a CE-marked (class 2a) portable medical device that uses pneumatic plethysmography. The device has 4 cuffs connected to the device which has a results screen. There is no need to rest before the test, but patients need to lie flat and remain still for the test, which takes 3 minutes. ABPI is automatically calculated by the device and the device can be set to classify the results into false high, normal, mild, moderate and severe according to local definitions. The device has an option for integrated printer and can be connected via USB cable to a computer with an optional reporting and database software package (DR4).

In addition to ABPI, the device also displays pulse waveforms. The manufacturer states that these can be interpreted by manually comparing them to the previously established 4-level grading system of Rumwell and McPharlin (1998). The presence of moderate or severe abnormality in the pulse waveforms reflects significant disease at the level of the cuff. The manufacturer notes that although pulse waveforms do not replace Doppler waveforms, they have been shown to have a high level of agreement. They state that pulse waveforms are very useful in patients with diabetes where the ABPI may be raised into the normal range due to calcification in the blood vessels, causing results to be misleading or unclear.

The Dopplex Ability Automatic ABI System is intended for use in people aged 18 and over. It should not be used in people with severe peripheral arterial disease (ankle systolic pressure less than 60 mmHg) and it is unable to determine ABPI if the ankle systolic pressure is above 205 mmHg. The Dopplex Ability device should not be used for people with the following conditions: suspected or present deep vein thrombosis (DVT), severe congestive cardiac failure or similar condition, pulmonary hypertension, and if either arm is affected by any of the following conditions: gangrene, recent skin graft, dermatitis, cellulitis or if any condition prevents the application of pressure cuffs to both arms, such as mastectomy. If either leg is affected by any of the following conditions the device cannot be used to determine the ABPI in that leg: gangrene, recent skin graft, dermatitis, cellulitis, untreated leg or foot wounds. But it may be used on the unaffected leg. The manufacturer indicates that minimal training is needed to use the device.

### **3 Target condition**

#### **3.1 Peripheral arterial disease**

Peripheral arterial disease is a common condition where a build-up of fatty deposits in the arteries restricts blood supply to leg muscles. The most common symptom is leg pain when walking that improves on resting (intermittent claudication), but many people have no symptoms at all.

Peripheral arterial disease can lead to serious complications such as chronic limb-threatening ischaemia where the loss of blood supply to the leg causes tissue to die and there is a risk of losing the leg. People with peripheral arterial disease have an increased risk of developing heart disease and stroke.

#### **3.2 Leg ulcers**

Leg ulcers are leg wounds that are slow to heal. They develop above the ankle but below the knee. It is estimated that about 1 million or 2% of adults in

the UK have a leg ulcer (Guest et al. 2020). Ulcers become more common with older age.

Most leg ulcers, about 70%, are venous leg ulcers. They develop because the veins in the leg do not work properly (venous insufficiency). About 10% of leg ulcers are caused by peripheral arterial disease only and in about 20% of ulcers the underlying cause is both venous and arterial disease.

In 2018 the [National Wound Care Strategy Programme](#), commissioned by NHS England and NHS Improvement, was set up to improve the care for people with leg ulcers and other chronic wounds.

### 3.3 Diagnostic and care pathway

The [National Wound Care Strategy Programme's \(NWCSP\) 2020 recommendations for lower limb ulcers](#) outline a pathway of care for leg ulcer care in the NHS. Clinical experts highlighted that this is aspirational and, while closely followed in some parts of the NHS, practice overall is very variable. In particular, achieving the recommended time to initial full clinical assessment was highlighted as a challenge.

Clinical experts commented that while leg ulcers are very unusual in children and less is known about their causes, the assessment and care of leg ulcers in children is similar, although rarer causes may be more likely to be considered in assessment.

#### 3.3.1 Immediate care before full clinical assessment and ulcer treatment

For immediate care of the ulcer, NWCSP guidance recommends cleaning the ulcer, applying emollient to moisturise the surroundings and covering the ulcer with a simple low adherent dressing.

People who have any of the following red flag symptoms should be immediately referred to a relevant clinical specialist:

- acute infection of leg or foot (treatment of an infected leg ulcer should follow the [NICE guideline for antimicrobial prescribing for leg ulcer infection \[NG152\]](#))
- symptoms of sepsis
- acute or chronic limb-threatening ischaemia
- suspected acute deep vein thrombosis, or
- suspected skin cancer



If there are no red flag symptoms, the [NWCSP](#) recommends applying first line, mild graduated compression until the full clinical assessment and decision on ulcer treatment (that is, before ankle brachial pressure index [ABPI] is measured). Clinical experts commented that in practice some practitioners are uncomfortable applying even mild compression without an ABPI measurement. When possible, people should be offered supported self-care.

For people in the last weeks of their life, input for an appropriate care plan should be sought from other clinicians involved in the person's care.

### 3.3.2 Full clinical assessment for ulcer treatment planning

Within 14 days of initial presentation, people with leg ulcers should be offered a full clinical assessment that covers their general health, the ulcer, and their leg ([NWCSP](#)). Experts noted that achieving this within 14 days is a challenge, and time to this appointment can be substantially longer in some parts of the UK. In areas where practitioners trained to do the manual doppler tests are scarce, referrals may need to be made to specialist vascular services to do this assessment. This assessment aims to identify underlying causes of the ulcer and to inform suitable treatment ([NWCSP](#)). It includes vascular assessment of arterial supply using ABPI.

The [NICE guideline on peripheral arterial disease \(CG147\)](#) recommends measuring ABPI by taking measurements manually using a doppler probe of suitable frequency in preference to an automated system. It also recommends documenting the nature of the doppler ultrasound signals in the foot arteries (pattern of the doppler waveforms). The type of waveform can provide information about the quality of arterial circulation and can identify issues even if a person has an ABPI that does not indicate arterial disease (for example for people with arterial calcification, described below).

For ABPI, the following measurements are taken:

- Systolic blood pressure in each arm
- Systolic blood pressure in at least 2 of the 3 main arteries in each ankle (posterior tibial and dorsalis pedis and where possible, also peroneal)

To calculate ABPI, the highest ankle pressure in a leg is divided by the highest of the 2 arm pressures. When arterial supply is healthy, the pressures are almost the same.

The [NICE clinical knowledge summary on interpretation of ABPI](#) suggests that the values are typically interpreted as:

- between 0.8 and 1.3 suggests no evidence of significant arterial disease
- between 0.5 and 0.79 suggests there are signs of arterial disease
- less than 0.5 suggests severe arterial disease

Experts noted that this may vary in practice; for example instead of 0.8 to 1.3, ABPI values between 0.85 or 0.9 to 1.25 are considered to suggest no sign of arterial disease. ABPI ranges used to assess arterial disease may vary for the different automated devices (see sections 2.2.1, 2.2.5 and 2.2.6).

In some people with diabetes, rheumatoid arthritis, systemic vasculitis, atherosclerotic disease, and advanced chronic renal failure, ABPI results may misleadingly appear normal or high because arteries have been hardened by calcium build up (arterial calcification) and are difficult to compress. In people with diabetes, diagnosis of peripheral arterial disease should not be excluded based on a normal or raised ABPI alone ([NICE guideline on peripheral arterial disease \[CG147\]](#)). Clinical experts highlighted the value of the information provided by a doppler waveform pattern in this situation to assess reliability of the ABPI score, although noting this can be difficult to interpret. The automated ABPI measurement technologies that do not use a doppler probe cannot provide doppler waveforms as an output. But some provide an alternative output that aims to provide information about the quality of arterial circulation in the ankles (see section 2). Clinical experts highlighted that it is uncertain if the information provided by these outputs is equivalent to doppler waveforms and noted that this information can be important to consider when making decisions about care. For ABPI values above 1.5 the vessels are likely to be incompressible and so the result cannot be relied on to guide clinical decisions. People with high ABPI values should be referred to a secondary care vascular service for further assessment. Experts mentioned that toe brachial index is sometimes measured in people with diabetes. [NICE guideline on peripheral arterial disease \[CG147\]](#) recommends further research on the effectiveness of this test in people with diabetes.

Experts noted that ABPI values should always be interpreted in the context of a full clinical assessment.

### *3.3.3 Treatment of venous leg ulcers and venous insufficiency*

The [NWCSF](#) recommends that treatment of venous leg ulcers should include strong compression therapy intended to apply compression of at least 40mmHg. This is consistent with the [SIGN clinical guideline for venous leg ulcers](#) that was in place since 2010 until withdrawal in August 2020. [An update of this guideline is currently being considered.](#)

People with venous leg ulcers who have chronic swelling of the ankle or leg that is not reduced when the leg is raised, abnormal leg shape or a very fragile skin, or whose ulcer oozes lots of fluid (exudate) should be offered strong multi-component compression bandaging. If these symptoms persist, advice and further assessment from experts should be sought ([NWCSP](#)).

Before offering compression therapy to people with advanced, unstable cardiac failure, their cardiac clinician should be consulted to avoid adding unnecessary cardiac burden.

Clinical experts highlighted that a normal ABPI can exclude arterial disease but does not diagnose venous insufficiency (which can also co-exist with arterial disease). The [NWCSP](#) recommends that people with venous leg ulcers should be referred to a secondary care vascular service for further assessment to decide on suitable treatment options to reduce the pressure in the veins of the leg. The vascular service may also re-measure ABPI. The further assessment of venous insufficiency is often done using duplex ultrasound. Treatment may include endothermal ablation and endovenous laser treatment of the long saphenous vein, ultrasound-guided foam sclerotherapy or surgery ([NICE's varicose veins guideline \(CG168\)](#)).

#### *3.3.4 Treatment of leg ulcers for people with suspected or confirmed arterial disease*

The [NWCSP](#) recommends that people with suspected or diagnosed arterial disease should be referred to a vascular service for further assessment of the arterial supply and advice on compression treatment (this may be reduced compression if arterial supply allows it). While waiting for the expert opinion, if there are no signs of arterial insufficiency, mild graduated compression should continue.

The vascular service may re-measure ABPI and will assess suitable treatment options to increase blood supply to the leg. Treatment offered may include a supervised exercise programme and revascularisation ([NICE guideline on peripheral arterial disease \[CG147\]](#)). Duplex ultrasound is used as first-line imaging to people for whom revascularisation is being considered, further imaging may include contrast-enhanced MR angiography or CT angiography ([NICE guideline on peripheral arterial disease \[CG147\]](#)). Experts noted that strong compression therapy may be applied after the blood supply has improved.

#### *3.3.5 Treatment of mixed leg ulcers*

Experts noted that when the underlying cause of the ulcer is both venous and arterial disease (mixed ulcer), treatment of the ulcer may first focus on either treating the arterial cause (see section 3.3.4) or the venous cause (see section 3.3.3). How the treatment is started depends on which cause is dominant. Experts highlighted that management can be very complex and would be done on a patient by patient basis.

### *3.3.6 Treatment of leg ulcers with other or uncertain cause*

A small proportion of leg ulcers are not venous, arterial or mixed ulcers. When this is the case or the cause of the ulcer is uncertain, people should be referred for a dermatology opinion (or other specialist depending on symptoms and service arrangements). While waiting for the specialist opinion, if there are no signs of arterial insufficiency, mild graduated compression should continue ([NWCSP](#)).

### *3.3.7 Treatment of leg ulcers in people with lymphoedema*

The [Lymphoedema Framework's international consensus on best practice for the management of lymphoedema](#) includes recommendations for treatment of leg ulcers for people with suspected lymphoedema. If arterial involvement is suspected, referral to a vascular specialist should be made before introducing compression. People with lymphoedema and ABPI between 0.5 and 0.8 should not receive sustained compression exceeding 25 mmHg. People with ABPI less than 0.5 should not receive compression.

### *3.3.8 Ongoing care and review of leg ulcers*

The [NWCSP](#) recommends that the effectiveness of the treatment plan should be reviewed at each dressing change and the healing of the leg ulcer assessed and documented at least every 4 weeks (and more often if there are concerns). Local specialist service should be contacted for advice for ulcers that are deteriorating or show no significant progress towards healing.

The [NWCSP](#) recommends that local specialist service team should also be contacted if the leg ulcer does not heal within 12 weeks and is either deteriorating or shows no significant progress towards healing. If at 12 weeks, the ulcer is progressing towards healing but remains unhealed, the full initial clinical assessment done to identify the cause for the ulcer (see section 3.3.2), including measurement of ABPI, should be offered again. Clinical experts noted that in practice this re-assessment may only happen if the ulcer is not showing signs of healing or if there are changes in leg symptoms.

### 3.3.9 *Review of healed leg ulcers*

The [NWCSP](#) recommends that people with healed leg ulcers should be offered advice on skin care, footwear, exercise and mobility, rest and limb elevation, nutrition and self-care and if appropriate, quitting smoking and losing weight.

People with healed venous leg ulcers and no symptoms of arterial insufficiency should continue wearing compression hosiery ([NWCSP](#)). A review every 6 months for replacement of compression garments and ongoing advice about prevention of recurrence should be offered. Experts highlighted that some pressure garments need changing every 3 months. Changes in leg symptoms or skin problems relating to hosiery should trigger the full clinical assessment that includes ABPI measurement.

## 3.4 Patient issues and preferences

People with leg ulcers may feel embarrassed by their condition and modify their behaviour to hide it. They may also be scared of hurting themselves and not go out or move as much as they would usually do. Leg ulcers can be very painful and prevent people from doing their daily activities. Having unhealed ulcers, especially if ulceration is complex or stays for a long time, may lead to anxiety, social isolation, depression and feeling exhausted. This can also delay treatment of other health issues if they cannot be addressed until a leg ulcer has healed.

Faster access to full clinical assessment would be beneficial because this would allow for earlier ulcer treatment and potentially improved patient outcomes. But missing any signs of peripheral arterial disease could lead to harms from incorrect treatment.

People with leg ulcers may be worried about automatically inflating blood pressure cuffs hurting them, where manual cuffs could be inflated more gradually. But they may also prefer that the cuffs are inflated and deflated only once and a test that takes less time or does not need lying down.

A patient expert stated that consistency in how assessment and care is provided across the NHS is important to people.

## 4 *Comparator*

Currently, measuring the ankle brachial pressure index (ABPI) as part of an initial clinical assessment for people with leg ulcers (see section 3.3.2) is done using a hand-held doppler ultrasound probe and a manually inflated blood

pressure cuff (sphygmomanometer). People who are having their ABPI measured need to lie down and remain still before and during the test. Experts noted that depending on the experience of the person doing the test, it can take between 30 minutes and 1 hour to complete. Doing the test may need the involvement of 2 people. The test includes patient resting time, locating arterial pulses, taking manual systolic pressure measurements first in the arms and then ankles, and calculating the ABPI.

The doppler waveform pattern can also be considered, and can identify issues even if a person has an ABPI that does not indicate arterial disease.

Where healthcare professionals trained in doing the full clinical assessment including ABPI are available, the assessment is typically done by district or community nurses at a person's home, care home or a leg ulcer clinic, or by practice nurses at GP practices. The setting depends on the person's ability to attend the assessment outside of their home and local service arrangements. The NHS's leg ulcer care service model is currently evolving. In some parts of the country, tissue viability, dermatology or vascular service-led leg ulcer clinics are in use, or are being implemented, and may already do, or increasingly do in the future, initial ABPI assessment. The [National Wound Care Strategy Programme \(NWCSP\)](#) is working with several NHS organisations to identify the most effective ways to implement their recommendations for lower limb ulcers. In areas where practitioners trained to do the manual doppler tests are scarce, after immediate care of the ulcer (see section 3.3.1), referrals may need to be made to specialist vascular services to do the full clinical assessment. The [Vascular Society of Great Britain and Ireland's provision of services for people with vascular disease 2021 document](#) describes vascular service as a team of healthcare professionals who manage disorders of arteries, veins and lymphatics. Specialist vascular services are often also asked to assess people with leg ulceration.

The NWCSP recommends that the full clinical assessment is done within 14 days of initial presentation (see section 3.3.2), but experts noted that achieving this is challenging and time to assessment can be much longer.

#### **4.1 Reference standard**

Clinical experts commented that imaging (including duplex ultrasound scan, MR angiography or CT angiography) is considered the gold standard for detecting peripheral arterial disease.

## 5 Scope of the assessment

**Table 1 Scope of the assessment**

<b>Decision question</b>	Are devices for automated assessment of ankle brachial pressure index a clinically and cost effective alternative to a manual doppler test for assessing ankle brachial pressure index (ABPI) and peripheral arterial disease in people with leg ulcers?
<b>Population</b>	<ul style="list-style-type: none"> <li>• People with leg ulcers who need assessment of ABPI</li> </ul> <p>Where data permits, the following subgroups may be considered:</p> <ul style="list-style-type: none"> <li>• People with leg ulcers who need assessment of ABPI as part of their initial assessment (see section 3.3.2)</li> <li>• People with leg ulcers or healed leg ulcers who need re-assessment of ABPI as part of monitoring (see sections 3.3.8 and 3.3.9)</li> <li>• People with diabetes, rheumatoid arthritis, systemic vasculitis, atherosclerotic disease, advanced chronic renal failure or other conditions in which arterial calcification is common</li> <li>• People with sickle cell disease</li> <li>• People who have had lymph nodes removed or damaged, limb amputation or other conditions where blood pressure cannot be measured on both arms or legs</li> </ul>
<b>Potential interventions</b>	<p>Measuring ABPI and assessing arterial circulation using any one of:</p> <ul style="list-style-type: none"> <li>• boso ABI-system 100 (BOSCH + SOHN)</li> <li>• BlueDop Vascular Expert (BlueDop Medical)</li> <li>• Dopplex Ability Automatic ABI System (Huntleigh Healthcare)</li> <li>• MESI mTABLET ABI (MESI)</li> <li>• MESI ABPI MD (MESI)</li> <li>• WatchBP Office ABI (Microlife)</li> <li>• WatchBP Office Vascular (Microlife)</li> </ul> <p>Decisions about care would be made using ABPI and any additional information provided by the tests used alongside all other information from the full clinical assessment.</p>

<b>Comparator</b>	<p>Measuring ABPI and assessing arterial circulation using a handheld doppler probe and manual blood pressure sphygmomanometer.</p> <p>This can be outside specialist vascular services (such as in community or primary care), or, if practitioners trained to do the manual doppler tests are scarce, in specialist vascular services (see sections 4 and 6.3).</p> <p>Decisions about care would be made using ABPI and any additional information provided by the tests (doppler waveform) used alongside all other information from the full clinical assessment.</p>
<b>Healthcare settings</b>	<ul style="list-style-type: none"> <li>• Community (including people’s homes, care homes, community hospitals, leg ulcer clinic)</li> <li>• Primary care (GP practice)</li> <li>• Secondary care</li> </ul>
<b>Outcomes</b>	<p>Intermediate measures for consideration may include:</p> <ul style="list-style-type: none"> <li>• Accuracy to detect peripheral arterial disease</li> <li>• Concordance between measurements by manual and automated devices</li> <li>• Concordance between measurements by different automated devices</li> <li>• Technical failure rate</li> <li>• Time to ulcer treatment</li> <li>• Time to ulcer healing</li> <li>• Number of referrals to specialist services (for example for ulcers that are not healing or to do ABPI assessment)</li> <li>• Number of hospitalisations</li> <li>• Number of leg amputations</li> <li>• Impact of test results on clinical decision-making (including outputs other than ABPI; for example, doppler waveform)</li> <li>• Time taken to complete the test and calculate ABPI</li> <li>• Resources needed to do the test (for example, number of people or grade of staff needed to do the test)</li> <li>• Rate of testing</li> <li>• Acceptability and experience of using the device</li> </ul> <hr/> <p>Clinical outcomes for consideration may include:</p> <ul style="list-style-type: none"> <li>• Morbidity (including any adverse events caused by assessment or treatment)</li> </ul>



	<ul style="list-style-type: none"> <li>• Mortality</li> </ul>
	<p>Patient-reported outcomes for consideration may include:</p> <ul style="list-style-type: none"> <li>• Health-related quality of life</li> <li>• Acceptability of test procedure using the device (including for example resting, lying down, staying still, blood pressure measurements) and patient experience</li> </ul>
	<p>Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include:</p> <ul style="list-style-type: none"> <li>• Cost of device (including any accessories needed to operate, and also service and maintenance costs)</li> <li>• Cost of doing and interpreting testing</li> <li>• Cost of staff training</li> <li>• Cost of further diagnostic tests</li> <li>• Cost of treatment (including costs of any adverse events)</li> </ul>
	<p>The cost-effectiveness of interventions should be expressed in terms of incremental cost per quality-adjusted life year.</p>
<b>Time horizon</b>	<p>The time horizon for estimating clinical and cost effectiveness should be long enough to reflect any differences in costs or outcomes between the technologies being compared.</p>

## **6 Other issues for consideration**

### **6.1 Experience and availability of healthcare professionals able to do the manual doppler test**

The experience and level of training of the healthcare professional doing a manual doppler test and the availability of healthcare professionals able to do a manual doppler test is likely to affect the impact of introducing the automated devices into NHS practice. If data allows, clinical and cost effectiveness analysis considering the expertise of the test user should be provided.

### **6.2 Average blood pressure from multiple ankle arteries**

A clinical expert highlighted that the automated technologies may average blood pressure from several arteries in the ankle. This may reduce detection of peripheral arterial disease if there is only a problem in 1 artery, compared to manual assessment using the doppler probe on the 3 arteries in the ankle separately.

### **6.3 Time to assessment, and place of assessment, based on which method of ABPI measurement is available**

Experts highlighted that time to initial assessment (including ABPI) in current practice can be very variable, and potentially much longer than the 14 weeks recommended by the NWCSP (see section 3.3.2). A possible benefit of the automated tests is making assessment quicker or easier to do (for example, removing the need to locate an artery) which could reduce time to initial assessment and consequently time to treatment, if a shortage of staff able to do manual doppler assessment is a barrier to ABPI being measured. Delayed assessment may lead to longer periods with sub-optimal compression or without compression. Experts highlighted that there may be a reluctance for some clinicians to start even mild compression (as recommended by the NWCSP) before an ABPI is done. Economic analysis should investigate any impact of reduced time to assessment that could be achieved if the automated devices are used. Clinical experts also commented that in areas where practitioners trained to do the manual doppler tests are scarce, people may be referred to specialist services without an ABPI measurement in order to do this assessment. Economic analysis should investigate the potential impact of automated devices on reducing the need for such referrals.

## **7 *Potential equality issues***

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

The risk of cardiovascular disease, including peripheral arterial disease, is greater in men, people from South Asian family background and in areas of socio-economic deprivation. The risk increases with age. People with diabetes have an increased risk of cardiovascular disease, including peripheral arterial disease.

People with sickle cell disease are prone to leg ulcers. Sickle cell disease is more common in people with an African or Caribbean family background.

Swelling of the leg, obesity or complex ulceration may make it difficult or painful to wear blood pressure cuffs. Some automated tests provide cuffless ankle pressure measurements and so might make doing the test more comfortable for these people.

Some people with leg ulcers may find it difficult to lie flat, in particular for the length of time it may take to rest before and do a manual doppler test. If

automated tests can make doing the test more comfortable or quicker they may have particular benefit for this group.

The tests may not be suitable or work accurately for people who have had lymph nodes removed or damaged (and are at risk of lymphoedema), limb amputation or other conditions where blood pressure cannot be measured on both arms or legs.

## **8 *Potential implementation issues***

According to clinical experts and companies, adopting the automated ABPI measurement devices does not require extensive training.

There are concerns about nurses becoming de-skilled in using manual dopplers with the increase in use of automated devices. Because less expertise may be needed to use the automated devices, people who are less experienced not just in measuring ABPI but also the rest of the ulcer assessment may be expected to do the assessments and make treatment decisions.

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## **Appendix A      Glossary of terms**

### **Acute or chronic limb-threatening ischaemia**

Loss of blood supply to the leg that causes body tissue in the leg to die. Limb-threatening ischaemia is sometimes called critical limb ischaemia.

### **Ankle brachial index (ABI)**

See ankle brachial pressure index test (ABPI).

### **Ankle brachial pressure index (ABPI)**

The ankle brachial pressure index is measured to diagnose peripheral arterial disease.

### **Deep vein thrombosis**

Deep vein thrombosis is a blood clot in a vein, usually the leg.

### **Lymphoedema**

Lymphoedema is a long-term condition that causes swelling in the body's tissues, usually in the arms or legs. It develops when the lymphatic system (network of channels and glands in the body that helps fight infection and remove excess fluid) does not work properly.

### **Sepsis**

Sepsis is a life-threatening reaction to an infection. It happens when the immune system overreacts to an infection and starts to damage the body's own tissues and organs. Sepsis is sometimes called septicaemia or blood poisoning.

### **Sickle cell disease**

Sickle cell disease is the name for a group of inherited health conditions that affect the red blood cells. People with sickle cell disease produce unusually shaped red blood cells that can cause problems because they do not live as long as healthy blood cells and can block blood vessels. Sickle cell disease is a serious and lifelong health condition.

### **Systolic blood pressure**

Blood pressure is a measure of the force that the heart uses to pump blood around your body. Systolic blood pressure is the pressure when the heart pushes blood out.

### **Vascular service**

The [Vascular Society of Great Britain and Ireland's provision of services for people with vascular disease 2021 document](#) describes vascular service as a team of healthcare professionals who manage disorders of arteries, veins and

lymphatics. Specialist vascular services are often also asked to assess people with leg ulceration.

## **Appendix B      Abbreviations**

ABI	Ankle brachial index
ABPI	Ankle brachial pressure index
NWCSP	National Wound Care Strategy Programme

## **Appendix C      References**

Guest J. F., Fuller G. W. and Vowden P. (2020) Cohort study evaluating the burden of wounds to the UK's National Health Service in 2017/2018: update from 2012/2013. *BMJ Open* 10:e045253.

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