

## Primary care service framework: peripheral arterial disease

### June 2009

#### 1. Preface

Narrowing of arteries throughout the body is most frequently due to atherosclerosis. When these fatty plaques affect the coronary or carotid arteries they can cause heart attacks or stroke respectively. Elsewhere in the body the narrowing is referred to as peripheral arterial disease (PAD). Most frequently the disease affects the legs and then may be either asymptomatic, limit walking due to pain (claudication), or produce gangrene resulting in either loss of limb or life. PAD is a marker for atherosclerotic disease elsewhere and is associated with significantly increased risk of ischaemic events such as heart attacks and stroke.

PAD is therefore important for a number of reasons - it is common and has the same aetiology as coronary disease or stroke, it has significant health impact upon patients, its effects are expensive for the nation, it is generally unrecognised by health policy makers, and may be poorly recognised and treated by health professionals.

The aim of this primary care service framework is to remedy the gap in both diagnosis and treatment of PAD, by supporting PCTs in commissioning an effective service to diagnose and manage symptomatic PAD.

PCTs may want to give serious consideration to linking services they commission to address PAD to their vascular check programme.

In line with world-class commissioning competencies, PCTs will need to give consideration to how they develop the market for this particular service, in terms of case finding, provider capacity and competency, as well as informing local people.

#### 2. Purpose of this primary care service framework

The purpose of this primary care service framework is to equip commissioners, providers and practitioners with the necessary background knowledge, service and implementation details to deliver a high quality service in primary care for symptomatic patients with PAD. This includes; diagnosis, symptom management and reduction of risk of disease progression and other cardiovascular disease.

### 3. Period of service

It is recommended that this service is commissioned for a period of three years initially, subject to satisfactory annual review. This is for the following reasons:

- To ensure a viable contract term for providers, given the relatively small number of symptomatic patients (circa 30 people in an average sized GP practice with a list size of 6000)
- This is a new service, and it may take time to build up a patient base and become established.

### 4. Scope and definition of service

- Whilst there is no specific age range, PAD is uncommon in the under-fifties and the incidence of the disease increases with age and risk factors, eg smoking, diabetes. It affects around 10% of people in their 60's rising to 29% of the over 75's. Higher rates are seen in people with diabetes and renal disease and in those who smoke. The high risk groups are indicated in the diagram in section 9.
- It would therefore be appropriate to target this service at symptomatic patients, particularly middle aged and elderly male and female patients and those with diabetes and other cardiovascular diseases .
- The NHS Health Check programme consists of a series of tests which are clinically and cost effective in terms of identifying individual risk of heart disease, diabetes, stroke and kidney disease. PAD is not part of this programme. Some PCTs may decide to extend their programme to include PAD, where they have particularly high risk groups within their population. Using the Edinburgh artery questionnaire with the risk assessment may be helpful addition <sup>1</sup> to enable this.
- The service may be provided at PCT, locality or practice level
- The service, or elements of it, may be commissioned from several types of provider – for example, GP practices, pharmacists or nurse-led services. It is recommended that the full service should only be commissioned from those GP practices performing at a satisfactory level according to locally agreed protocols. These might include:
  - Open list
  - Meeting access standards
  - Low levels of patient complaints
  - No evidence of unusual unjustified referral patterns
  - Meeting prescribing targets
  - Good QOF performance

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<sup>1</sup> Fowkes FG, Housley E, Cawood EH, Macintyre CC, Ruckley CV, Prescott RJ. Edinburgh Artery Study: prevalence of asymptomatic and symptomatic peripheral arterial disease in the general population. Int J Epidemiol. 1991 Jun;20(2):384-92

- Evidence of previous successful delivery of other enhanced services
- Adequate premises
- This primary care service should not be confused with (and sits outside of) essential and additional GMS or PMS services already provided, current Quality and Outcomes (QOF) indicators and any National Enhanced Services.
- Exclusions: asymptomatic patients (ie those without claudication or critical limb ischaemia) are excluded from this Framework

## 5. Parties to the agreement

*For example:*

*Names of any accountable individuals and organisation details.*

## 6. Background

In the UK, at least 720,000 people suffer from symptomatic PAD and over 102,000 people are newly diagnosed with PAD each year. Approximately 5% of people over the age of 60 years – around 600,000 people in the UK – suffer from intermittent claudication as a result of PAD.

The large global REACH Registry showed that one in five patients with PAD suffered CV death, heart attack, stroke or hospitalisation after just one year of follow-up<sup>2</sup>

Furthermore, in the UK, one in six people over the age of 55 years have some degree of PAD. Incidence increases with age and, by the time they reach 70 years, around 15-20% of people will have some form of PAD. However, it is estimated that over half of all people with PAD do not have the diagnosis made; the first indication that they have PAD vascular disease may be when they have a heart attack or stroke. This is because only one third of all patients with PAD present with the classical symptoms of intermittent claudication, the remainder are asymptomatic, have atypical pain, or believe their symptoms are unimportant and are just a function of increasing age. PAD develops gradually and can remain unnoticed for long periods. In many cases, it may be asymptomatic. The rate at which the disease develops can vary significantly depending on the individual and when the symptoms do appear they can contribute to a very poor quality of life.

The commonest presenting symptom of PAD is cramp-like pain, typically in the calf muscles, brought on by walking and relieved by rest (intermittent claudication). The narrowed arteries restrict blood flow and muscle oxygen supply. As the disease progresses the pain may increase in severity and walking distance decreases. This can lead to major restrictions in the individual's lifestyle and employability.

More severe PAD results in inadequate blood flow to leg even at rest. In addition to pain when walking

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<sup>2</sup> Steg PG, Bhatt DL, Wilson PW et al. One-year cardiovascular event rates in outpatients with atherothrombosis. JAMA. 2007;297:1197-1206

(claudication), people with more severe PAD may experience pain even at rest, particularly at night. Without intervention this can lead to ulceration, infections and permanent tissue damage. In the worst cases, gangrene occurs and amputation may be necessary if adequate blood flow cannot be restored.

## 7. Summary of local need

*For example:*

*A detailed summary of local health and social care service needs drawn from a joint strategic needs assessment, done with Local Authority partners.*

*The evidence suggests that PAD affects men as much as women, and is a disease predominantly of older people. There is evidence for geographical variations that are linked to socio-economic conditions<sup>3</sup>. PCTs will want to ensure that their needs assessment supports the commissioning of a service that does not widen the inequality gap.*

## 8. Service objectives and intended health outcomes

The service objective is to deliver a diagnostic and management programme for patients with symptomatic PAD. Some of these patients will have co-morbidities, so are likely to be already known to their GP practice. However, it is important to pick up those people (the “not known” group) who have not been identified. These people might also be identified by other health care professionals (eg pharmacists or podiatrists) and will need to be referred for diagnosis, risk assessment and/or treatment.

Providers will be expected to demonstrate how they will deliver this objective, to ensure:

- The service is targeted appropriately and reduces, rather than widens, existing health inequalities
- There are clear protocols for dealing with the “not known” group so that these people can easily be referred into the service
- There are clear criteria for referral to secondary care
- The service dovetails with existing networks of provision, avoiding duplication/overlap. In particular, providers will need to show how they plan to:
  - minimise repeated checks on the same patient
  - manage data input, data exchange and confidentiality issues
- Compliance with agreed local protocols

The intended health outcomes include:

- Reduced risk of a serious or fatal cardiovascular event

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<sup>3</sup> DN: Reference needed

- Reduced risk of illness and incapacity
- Reduced risk of hospital admission and/or minimally invasive therapy (e.g. angioplasty, stenting) or surgery (eg amputation, lower limb arterial surgery)
- Improvement in the patient's quality of life in the longer term, and that of their family/carers

## 9. Service outline

The service will involve:

- Establishing a disease register, identifying new patients and putting them on the register
- Diagnosis of lower limb PAD, using measurement of ankle brachial pressure index (ABPI)
- Cardiovascular risk assessment and monitoring/follow up of risk factor modification
- Managing/alleviating current symptoms (eg pain, mobility)
- Reducing disease progression and major complications
- Sharing good practice, learning and skills with other providers in the local health community in order to ensure continuity and stability in the local workforce

Certain elements of this service - for example, cardiovascular risk assessment – are likely to be already in place. PCTs should ensure that in commissioning this service, they only fund the additional elements, namely:

- Equipment - Doppler ultrasound with 8 MHz probe.
- Nurse training and time to undertake ABPI measurement and Edinburgh Artery Questionnaire
- GP time to interpret and review the results

PCTs may wish to consider putting in place an awareness raising campaign, especially hard to reach groups.

PCTs will need to ensure that clear pathways are in place for referral for imaging and further management as we discussed on the day and

Any primary care based service should be integrated with local vascular services.

The diagram below<sup>4</sup> describes the patient pathway.

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<sup>4</sup> Dragging their feet: the cost of sub-optimal treatment for patients diagnosed with peripheral arterial disease. Target PAD June 2008  
<http://www.targetpad.co.uk/documents/DraggingTheirFeetReport.pdf>

# Primary Care Algorithm

Supported by an educational grant from sanofi-aventis and Bristol-Myers Squibb

## A. Does this patient have leg pain caused by PAD?

Note: High risk groups are as follows:

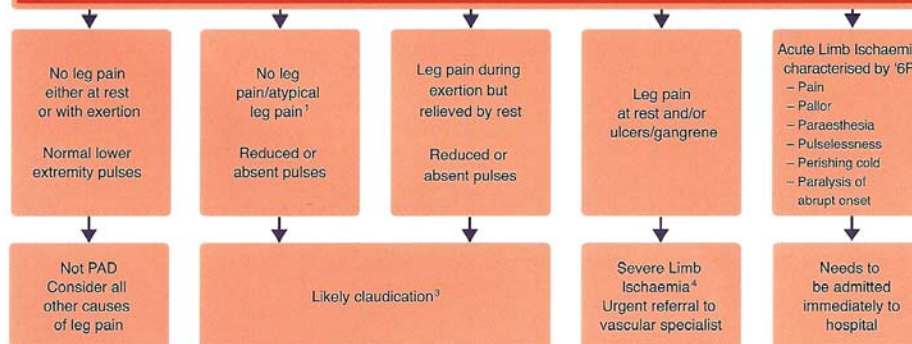
Age < 50 years with diabetes and one other atherosclerotic risk factor

Age 50 – 69 years with a history of smoking or diabetes

Age > 70 years

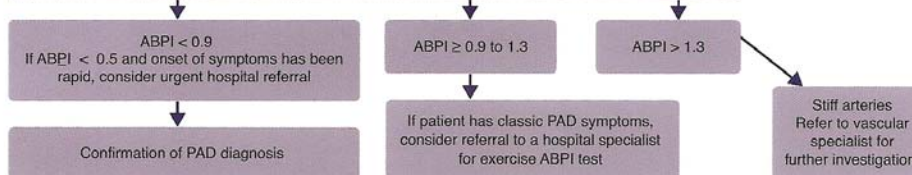
Known to have atherothrombosis in any vascular bed

## B. Assess symptoms and signs

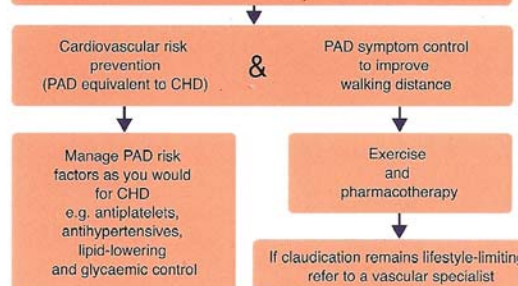


## C. Measure Ankle-Brachial Pressure Index (ABPI)<sup>5</sup>

(See overleaf)



## D. Treatment of PAD<sup>6</sup>



<sup>1,2,3,4,6</sup> – Refer to relevant sections overleaf

CV 08/1064

Date of preparation: October 2008

## 10. Location of service

The service will be provided from suitable premises - GP practice, community clinic (subject to minimum local and statutory requirements) and may also be delivered in the patient's own home.

**Equipment** – the provider will provide (and maintain/calibrate to the appropriate standards all necessary equipment)

## 11. Integrated governance

**Clinical Governance** - arrangements must be proportionate to the service provided and comply with any local expectations or requirements of the commissioner.

Any commissioned service must meet all current quality requirements. Compliance with relevant NICE guidance is also required.

**Professional competency, education and training** - ABPI measurements should be undertaken by suitably trained persons who have been deemed competent by local experts.

**Patient, public and staff safety** – Providers will be required to demonstrate that evidence based clinical guidelines are being used. Providers should have in place appropriate health and safety and risk management systems and that premises standards are met. They should also ensure that any risk assessments and significant events are both documented and audited regularly and outcomes of these implemented. Services should comply with national requirements for recording, reporting, investigation and implementation of learning from incidents. Further details can be found on the National Patient Safety Agency website [www.npsa.nhs.uk](http://www.npsa.nhs.uk)

The provider of this service is also required to have in place effective policies and procedures which promote the well being and safety of service users and staff. Providers should ensure safe staffing capacity at all times and staff should be able to demonstrate that they have participated in organisational mandatory and update training, for example infection control, manual handling, risk assessment as required.

The provider will ensure that staff undertaking patient assessments will have full CRB checks/clearance

**Information management** - Any communications strategy or provision should be coherent with and follow local policies and the NHS Confidentiality Code if Practice, vulnerable adult protection procedures, and should outline the mechanisms to safeguard patient information when shared within an integrated service. Procedures should be put in place to obtain patient consent for onward transmission of their records. Providers should comply with the PCT's policies on secure data transmission.

**Equipment** – specification for equipment for measuring resting ABPIs

Hand-held doppler:

A number of models are available: some models have a stand, but this is not usually necessary as the handheld can be rested on the couch next to the patients legs. However, consideration may be given to mounting the handheld on the same stand as the sphygmomanometer.

Essential:

- For peripheral vascular work an 8MHz pencil probe should be used

Desirable:

- Headphone socket and headphones to increase ease in picking up faint signals
- Bi-directional flow to aid identification of arteries from veins in very poor flow situations
- Re-chargeable battery system with re-charger

Sphygmomanometer

- A normal manual sphygmomanometer mounted on a stand to allow easy movement round the patient's couch should be adequate.
- The reading should be clear to see when standing to operate the handheld Doppler and sphygmomanometer pressure release valve.
- The valve should be easy to operate to allow controlled slow release of pressure single handed (right or left)
- A 14cm (5 2") cuff is used for ABPI measurement.

Other supplies

- Spare batteries
- Ultrasound gel
- Paper wipes

**Clinical audit and review** – Providers will be required to demonstrate their coordination of and involvement in regular inter-professional and inter-agency meetings and regular clinical audit of the service interventions and outcomes such as drug therapies or well-being and behaviour changes. This audit can be carried out by extracting data using the Read codes.

**Patient and Public Involvement** - Providers will be required to demonstrate active engagement with patients and local communities in commissioning and developing services, self care plans or in supporting patients to utilise self care opportunities. Providers should demonstrate how systematic patient feedback is being used to shape and improve services. Involving family carers and supporters will help deliver the components within this service specification. Local Involvement Networks (LINKs), the voluntary sector and patient advocacy organisations are all further mechanisms to seek active involvement in service planning, delivery and monitoring.

**Equality and Human Rights** - Delivering good quality care will require organisations to demonstrate competence in identifying and taking action on inequality and also needing to engage with communities that have not found accessing public services easy. Undertaking Equality Impact Assessments (EQIAs) is a specific legal obligation, and conducting EQIAs and using the evidence to create a meaningful dialogue with communities (especially seldom heard from groups) is central to effective commissioning and service provision. This will create an evidence-based approach. As a minimum, core standard C7e of Standards for Better Health stipulates “healthcare organisations should enable all members of the population to access services equally and offer choice in access to services and treatment equitably”. To assist this process, organisations may wish to refer to ‘Creating a Disability Equality Scheme: a Practical Guide for the NHS’ -

[www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4139666](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4139666).

**Managing complaints** – Responsive protocols and procedures should be in place for managing patient complaints. These should be available in ‘easy read’ format so they are accessible to people with limited communication skills. Complaints should be reviewed at regular intervals and learning from these shared and applied as appropriate to ensure that services are continually improved.

**Continuous quality improvement** – a set of indicators should be selected or developed and then agreed which defines the key quality requirements of the service. The service should also identify how it uses these measures and others to ensure that the quality of the service is continuously improved.

## 12. Information management

The provider will maintain a disease register for patients with a confirmed diagnosis of PAD. This will be a tiered approach similar to that for coronary-artery disease (CAD) and record data such as:

- Cholesterol
- Blood sugar
- Blood pressure
- Walking distance to claudication (patient reported)
- Numbers of patients who have had ABPI
- Numbers of patients with confirmed diagnosis of PAD

The register will need to take account of local protocols and guidelines eg for the treatment of lipids. It is recommended that using the register, the provider will need to demonstrate improvement year on year

Year 1: 40%

Year 2: 60%

Year 3: 80%

using the QOF indicators for cholesterol and hypertension, including tighter controls for people with diabetes.

It should be noted that Patient Reported Outcome Measures (PROMs) should be treated with caution here: the aim is to produce risk factor modification for the underlying vascular disease and therefore reduce mortality; as a result patients may not actually feel any better as on treatment.

### 13. Service Monitoring and Evaluation

Service providers will need to demonstrate the effectiveness of the service to commissioners possibly at regular times during the year and, at the least, on an annual basis. This will need to be provided to the commissioners in an annual report, which will inform any annual review process or meeting. The process by which this evaluation is achieved can also be used to show the outcomes of the service to other key stakeholders such as patients and family carers. Service evaluation should be built in from the commencement of any service and should cover, as a minimum, the following areas:

- **Service activity** – Volume of work against any agreed activity levels and distance from profile, capacity, needs and demand analyses, workforce arrangements, real time referral data to other care pathways or appropriate agencies recorded in the GP system using the appropriate Read codes.
- **Clinical outcomes** – Regular analysis and interpretation of clinical outcomes data as well as regular analysis and interpretation of PPA data for prescribing.
- **Quality and governance** – Quality criteria will need to be established (in agreement with commissioners) and measured with standards needing to be met on a continual basis. Results of clinical audits will be used to inform service provision during the year. EQIA data should be used to underpin local integrated service provision.
- **Patient experience** – Patients views on their experiences and satisfaction levels will need to be measured through an on-going, systematic process to test whether the service is engaging with patients, family carers and supporters in a way that supports them. Different and innovative approaches to obtaining these views and experiences will be necessary. As indicated in Section 12, PROMs are unlikely to be reliable indicators for patients with PAD. Leg pain/mobility is the key quality of life issue for patients; however, the treatment of vascular risk in PAD patients may of itself reduce quality of life in the short term (due to potential adverse drug reactions) whilst it is invaluable in preventing serious future events. This will need to be explained to patients. Similarly, the quality of life measures in the 18 weeks commissioning pathway template are neither relevant nor practical for PAD. The approached processes should also be stratified where possible to show any differential impact on disadvantaged groups (e.g. Black and Minority Ethnic groups, deprived groups, males, females etc) and any resultant service changes (planned or achieved) should be highlighted.
- **Value for money** – Cost effectiveness or 'best value' analyses of the primary service outcomes in relation to

comparative costs of hospital activity or those services providing equivalent quality of care. Such measures could include attendance rates, waiting times, length of stay. Other possible analyses include: - Prescribing costs; benefits of increase in social capital and active citizenship; Staff and non-staff costs of running the service; Capital costs etc.

#### **14. Funding**

*There will be no fixed or nationally agreed price for this service. Commissioners and providers may wish to access alternative funding mechanisms, such as local programme budgeting along the whole patient pathway, and should agree funding which is reflective of the level of service to be delivered locally and could include:*

- *Basic funding for achieving minimum requirements within the service specification*
- *Additional funding or financial incentive for delivering specific local patient outcomes*
- *Indication of national benchmark prices if available*

#### **15. Contract Management**

*For example:*

*Name and contact point of the contract manager of both the commissioner and provider. Any specific local arrangements for contract management should also be stated.*

**16.**  
**Review, variation and re-commissioning process**

In their agreement with practices PCTs may want to consider the inclusion of the following clauses/arrangements

**Suspension arrangements**

*Payments under the scheme will be suspended if at any time the contract holder is unable to provide services in line with the agreed service specification.*

*Before any suspension the contract holder and PCT will meet discuss the reason for the suspension identifying any possible resolution.*

*If the matter is not resolved the PCT will issue a suspension notice to the contract holder within 7 days.*

**Notice period**

*Either party may exit the agreement by giving 3 months written notice.*

**Decommissioning**

Arrangements for the exit of the contract holder from the agreement whether it is due to termination or because the agreement has come to an end should be included. The inclusion of an exit plan that details the processes to manage the exit of the contract holder from performing the Services is recommended.

**Termination**

*The PCT may terminate the scheme within 28 days if, following suspension of payments the contract holder fails to re-establish services according to the service specification or take appropriate action to address deficiencies within eligibility criteria.*

*Before issuing an exit notice, the parties will meet to discuss the reason for termination.*

*If after this meeting the reason for terminating is not resolved then the relevant party will issue an exit notice.*

*The PCT right to claw-back monies as a result of underperformance or failure to deliver on agreed action plans shall survive the termination of this agreement.*

**Appeal procedures**

*Either party can appeal against a suspension or termination notice using the contractual dispute resolution procedures, or, where that is not appropriate, the Trust Contract Appeals process*

**Review and Variation**

Feedback from service users should support the review process and arrangements for incorporating changes resulting from this should be included.

**17. Signatories**

*Signatures from both parties as those accountable for the agreement*

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## Additional Supporting Information

Patient leaflet: What is Peripheral Arterial Disease, Target PAD, January 2007

Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG; TASC II Working Group, Bell K, Caporusso J, Durand-Zaleski I, Komori K, Lammer J, Liapis C, Novo S, Razavi M, Robbs J, Schaper N, Shigematsu H, Sillesen H, Sapoval M, White C, White J; TASC II Working Group. (2007). Inter-Society Consensus for the Management of Peripheral Arterial Disease. *Int Angiol.* 26 (2): 81-157. PMID 17489079

Fowkes FG, Housley E, Cawood EH, Macintyre CC, Ruckley CV, Prescott RJ. Edinburgh Artery Study: prevalence of asymptomatic and symptomatic peripheral arterial disease in the general population. *Int J Epidemiol.* 1991 Jun;20(2):384-92

Gibbons, Jonathan L et al, Guidelines for the Management of Patients With Peripheral Arterial Disease) ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop for Vascular Medicine and Biology, Society of Interventional Radiology, and the Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society Collaborative Report from the American Association for Vascular Surgery/Society for Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic): A ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial *J. Am. Coll. Cardiol.* 2006;47;1-192

SIGN 89 Diagnosis and management of peripheral arterial disease. A national guideline. October 2006  
<http://www.sign.ac.uk/guidelines/fulltext/89/index.html>

Dragging their feet: the cost of sub-optimal treatment for patients diagnosed with peripheral arterial disease. Target PAD June 2008  
<http://www.targetpad.co.uk/documents/DraggingTheirFeetReport.pdf>

The Provision of Services for Patients with vascular Disease, Vascular Society of Great Britain and Ireland, 2009  
<http://www.library.nhs.uk/Vascular/ViewResource.aspx?resID=304456>