



# Peripheral arterial disease: diagnosis and management

Clinical guideline
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## Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

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This guideline is the basis of QS52.

#### Introduction

Lower limb peripheral arterial disease (called peripheral arterial disease throughout this document) is a marker for increased risk of cardiovascular events even when it is asymptomatic. The most common initial symptom of peripheral arterial disease is leg pain while walking, known as intermittent claudication. Critical limb ischaemia is a severe manifestation of peripheral arterial disease, and is characterised by severely diminished circulation, ischaemic pain, ulceration, tissue loss and/or gangrene.

The incidence of peripheral arterial disease increases with age. Population studies have found that about 20% of people aged over 60 years have some degree of peripheral arterial disease. Incidence is also high in people who smoke, people with diabetes and people with coronary artery disease. In most people with intermittent claudication the symptoms remain stable, but approximately 20% will develop increasingly severe symptoms with the development of critical limb ischaemia.

Mild symptoms are generally managed in primary care, with referral to secondary care when symptoms do not resolve or deteriorate. There are several treatment options for people with intermittent claudication. These include advice to exercise, management of cardiovascular risk factors (for example, with aspirin or statins) and vasoactive drug treatment (for example, with naftidrofuryl oxalate).

People with severe symptoms that are inadequately controlled are often referred to secondary care for assessment for endovascular treatment (such as angioplasty or stenting), bypass surgery, pain management and/or amputation.

Rapid changes in diagnostic methods, endovascular treatments and vascular services, associated with the emergence of new sub-specialties in surgery and interventional radiology, has resulted in considerable uncertainty and variation in practice. This guideline aims to resolve that uncertainty and variation.

## Drug recommendations

The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

#### Patient-centred care

This guideline offers best practice advice on the care of adults aged 18 years or over with peripheral arterial disease.

Treatment and care should take into account patients' needs and preferences. People with peripheral arterial disease should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If patients do not have the capacity to make decisions, healthcare professionals should follow the <u>Department of Health's advice on consent</u> and the <u>code of practice that accompanies the Mental Capacity Act</u>. In Wales, healthcare professionals should follow <u>advice on consent from the Welsh Government</u>.

Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's needs. Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

If the patient agrees, families and carers should have the opportunity to be involved in decisions about treatment and care.

Families and carers should also be given the information and support they need.

## Key priorities for implementation

The following recommendations have been identified as priorities for implementation.

#### Information requirements

- Offer all people with peripheral arterial disease oral and written information about their condition. Discuss it with them so they can share decision-making, and understand the course of the disease and what they can do to help prevent disease progression. Information should include:
  - the causes of their symptoms and the severity of their disease
  - the risks of limb loss and/or cardiovascular events associated with peripheral arterial disease
  - the key modifiable risk factors, such as smoking, control of diabetes, hyperlipidaemia, diet, body weight and exercise (see also recommendation on the secondary prevention of cardiovascular disease below)
  - how to manage pain
  - all relevant treatment options, including the risks and benefits of each
  - how they can access support for dealing with depression and anxiety.

Ensure that information, tailored to the individual needs of the person, is available at diagnosis and subsequently as required, to allow people to make decisions throughout the course of their treatment.

#### Secondary prevention of cardiovascular disease in people with peripheral arterial disease

- Offer all people with peripheral arterial disease information, advice, support and treatment regarding the secondary prevention of cardiovascular disease, in line with published NICE guidance (see <u>related NICE guidance</u>) on:
  - smoking cessation
  - diet, weight management and exercise
  - lipid modification and statin therapy

- the prevention, diagnosis and management of diabetes
- the prevention, diagnosis and management of high blood pressure
- antiplatelet therapy.

#### Diagnosis

- Assess people for the presence of peripheral arterial disease if they:
  - have symptoms suggestive of peripheral arterial disease or
  - have diabetes, non-healing wounds on the legs or feet or unexplained leg pain or
  - are being considered for interventions to the leg or foot or
  - need to use compression hosiery.
- Assess people with suspected peripheral arterial disease by:
  - asking about the presence and severity of possible symptoms of intermittent claudication and critical limb ischaemia
  - examining the legs and feet for evidence of critical limb ischaemia, for example ulceration
  - examining the femoral, popliteal and foot pulses
  - measuring the ankle brachial pressure index (see recommendation below).
- Measure the ankle brachial pressure index in the following way:
  - The person should be resting and supine if possible.
  - Record systolic blood pressure with an appropriately sized cuff in both arms and in the posterior tibial, dorsalis pedis and, where possible, peroneal arteries.
  - Take measurements manually using a Doppler probe of suitable frequency in preference to an automated system.
  - Document the nature of the Doppler ultrasound signals in the foot arteries.
  - Calculate the index in each leg by dividing the highest ankle pressure by the highest arm pressure.

#### Imaging for revascularisation

• Offer contrast-enhanced magnetic resonance angiography to people with peripheral arterial disease who need further imaging (after duplex ultrasound) before considering revascularisation.

#### Management of intermittent claudication

• Offer a supervised exercise programme to all people with intermittent claudication.

#### Management of critical limb ischaemia

- Ensure that all people with critical limb ischaemia are assessed by a vascular multidisciplinary team before treatment decisions are made.
- Do not offer major amputation to people with critical limb ischaemia unless all options for revascularisation have been considered by a vascular multidisciplinary team.

#### 1 Guidance

The following guidance is based on the best available evidence. The <u>full guideline</u> gives details of the methods and the evidence used to develop the guidance.

## 1.1 Information requirements

- 1.1.1 Offer all people with peripheral arterial disease oral and written information about their condition. Discuss it with them so they can share decision-making, and understand the course of the disease and what they can do to help prevent disease progression. Information should include:
  - the causes of their symptoms and the severity of their disease
  - the risks of limb loss and/or cardiovascular events associated with peripheral arterial disease
  - the key modifiable risk factors, such as smoking, control of diabetes, hyperlipidaemia, diet, body weight and exercise (see also <u>recommendation 1.2.1</u>)
  - how to manage pain
  - all relevant treatment options, including the risks and benefits of each
  - how they can access support for dealing with depression and anxiety.

Ensure that information, tailored to the individual needs of the person, is available at diagnosis and subsequently as required, to allow people to make decisions throughout the course of their treatment.

1.1.2 NICE has produced guidance on the components of good patient experience in adult NHS services. Follow the recommendations in <u>patient experience in adult NHS services</u> (NICE guideline CG138).

## 1.2 Secondary prevention of cardiovascular disease in people with peripheral arterial disease

1.2.1 Offer all people with peripheral arterial disease information, advice, support and treatment regarding the secondary prevention of cardiovascular disease, in line with published NICE guidance (see <u>related NICE guidance</u>) on:

- smoking cessation
- diet, weight management and exercise
- lipid modification and statin therapy
- the prevention, diagnosis and management of diabetes
- the prevention, diagnosis and management of high blood pressure
- antiplatelet therapy.

## 1.3 Diagnosis

- 1.3.1 Assess people for the presence of peripheral arterial disease if they:
  - have symptoms suggestive of peripheral arterial disease or
  - have diabetes, non-healing wounds on the legs or feet or unexplained leg pain or
  - are being considered for interventions to the leg or foot or
  - need to use compression hosiery.
- 1.3.2 Assess people with suspected peripheral arterial disease by:
  - asking about the presence and severity of possible symptoms of intermittent claudication and critical limb ischaemia
  - examining the legs and feet for evidence of critical limb ischaemia, for example ulceration
  - examining the femoral, popliteal and foot pulses
  - measuring the ankle brachial pressure index (see recommendation 1.3.3).
- 1.3.3 Measure the ankle brachial pressure index in the following way:
  - The person should be resting and supine if possible.
  - Record systolic blood pressure with an appropriately sized cuff in both arms and in the posterior tibial, dorsalis pedis and, where possible, peroneal arteries.

- Take measurements manually using a Doppler probe of suitable frequency in preference to an automated system.
- Document the nature of the Doppler ultrasound signals in the foot arteries.
- Calculate the index in each leg by dividing the highest ankle pressure by the highest arm pressure.

### 1.4 Imaging for revascularisation

- 1.4.1 Offer duplex ultrasound as first-line imaging to all people with peripheral arterial disease for whom revascularisation is being considered.
- 1.4.2 Offer contrast-enhanced magnetic resonance angiography to people with peripheral arterial disease who need further imaging (after duplex ultrasound) before considering revascularisation.
- 1.4.3 Offer computed tomography angiography to people with peripheral arterial disease who need further imaging (after duplex ultrasound) if contrast-enhanced magnetic resonance angiography is contraindicated or not tolerated.

## 1.5 Management of intermittent claudication

#### Supervised exercise programme

- 1.5.1 Offer a supervised exercise programme to all people with intermittent claudication.
- 1.5.2 Consider providing a supervised exercise programme for people with intermittent claudication which involves:
  - 2 hours of supervised exercise a week for a 3-month period
  - encouraging people to exercise to the point of maximal pain.

#### Angioplasty and stenting

1.5.3 Offer angioplasty for treating people with intermittent claudication only when:

- advice on the benefits of modifying risk factors has been reinforced (see recommendation 1.2.1) and
- a supervised exercise programme has not led to a satisfactory improvement in symptoms and
- imaging has confirmed that angioplasty is suitable for the person.
- 1.5.4 Do not offer primary stent placement for treating people with intermittent claudication caused by aorto-iliac disease (except complete occlusion) or femoro-popliteal disease.
- 1.5.5 Consider primary stent placement for treating people with intermittent claudication caused by complete aorto-iliac occlusion (rather than stenosis).
- 1.5.6 Use bare metal stents when stenting is used for treating people with intermittent claudication.

#### Bypass surgery and graft types

- 1.5.7 Offer bypass surgery for treating people with severe lifestyle-limiting intermittent claudication only when:
  - angioplasty has been unsuccessful or is unsuitable and
  - imaging has confirmed that bypass surgery is appropriate for the person.
- 1.5.8 Use an autologous vein whenever possible for people with intermittent claudication having infra-inguinal bypass surgery.

#### Naftidrofuryl oxalate

- 1.5.9 Consider naftidrofuryl oxalate for treating people with intermittent claudication, starting with the least costly preparation, only when:
  - supervised exercise has not led to satisfactory improvement and
  - the person prefers not to be referred for consideration of angioplasty or bypass surgery.

Review progress after 3–6 months and discontinue naftidrofuryl oxalate if there has been no symptomatic benefit.

### 1.6 Management of critical limb ischaemia

1.6.1 Ensure that all people with critical limb ischaemia are assessed by a vascular multidisciplinary team before treatment decisions are made.

#### Revascularisation

- 1.6.2 Offer angioplasty or bypass surgery for treating people with critical limb ischaemia who require revascularisation, taking into account factors including:
  - comorbidities
  - pattern of disease
  - availability of a vein
  - patient preference.
- 1.6.3 Do not offer primary stent placement for treating people with critical limb ischaemia caused by aorto-iliac disease (except complete occlusion) or femoro-popliteal disease.
- 1.6.4 Consider primary stent placement for treating people with critical limb ischaemia caused by complete aorto-iliac occlusion (rather than stenosis).
- 1.6.5 Use bare metal stents when stenting is used for treating people with critical limb ischaemia.
- 1.6.6 Use an autologous vein whenever possible for people with critical limb ischaemia having infra-inguinal bypass surgery.

#### Management of critical limb ischaemic pain

1.6.7 Offer paracetamol, and either weak or strong opioids depending on the severity of pain, to people with critical limb ischaemic pain.

- 1.6.8 Offer drugs such as laxatives and anti-emetics to manage the adverse effects of strong opioids, in line with the person's needs and preferences.
- 1.6.9 Refer people with critical limb ischaemic pain to a specialist pain management service if any of the following apply:
  - their pain is not adequately controlled and revascularisation is inappropriate or impossible
  - ongoing high doses of opioids are required for pain control
  - pain persists after revascularisation or amputation.
- 1.6.10 Do not offer chemical sympathectomy to people with critical limb ischaemic pain, except in the context of a clinical trial.

#### Major amputation

1.6.11 Do not offer major amputation to people with critical limb ischaemia unless all options for revascularisation have been considered by a vascular multidisciplinary team.

## 2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a <u>scope</u> that defines what the guideline will and will not cover.

#### The guideline covers

- Adults aged 18 and older.
- People who present with symptoms of lower limb peripheral arterial disease, including intermittent claudication, ischaemic rest pain, and/or tissue loss.
- People without symptoms of peripheral arterial disease (for example, those with venous ulceration) who have abnormal ankle brachial pressure index.
- Subgroups based on ethnicity, socioeconomic factors, age or comorbidities (including people with diabetes), for which differences in management and outcome are identified.

#### The guideline does not cover

- Children and young people aged 17 and younger.
- Adults who have acute ischaemia of the lower limb.
- Methods of amputation and rehabilitation.
- Management of diabetic foot problems.
- Use of topical treatments and dressings.

#### How this guideline was developed

NICE commissioned the National Clinical Guideline Centre to develop this guideline. The Centre established a Guideline Development Group (see <u>appendix A</u>), which reviewed the evidence and developed the recommendations.

There is more information about how NICE guidelines are developed on the NICE website.

## 3 Implementation

NICE has developed tools to help organisations implement this guidance.

#### 4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline (see section 5).

## 4.1 Angioplasty versus bypass surgery for treating people with critical limb ischaemia caused by disease of the infra-geniculate arteries

What is the clinical and cost effectiveness of a 'bypass surgery first' strategy compared with an 'angioplasty first' strategy for treating people with critical limb ischaemia caused by disease of the infra-geniculate (below the knee) arteries?

#### Why this is important

Many people with critical limb ischaemia, especially those with diabetic vascular disease, also have disease of the infra-geniculate (below the knee) arteries in the calf. For many years, the standard of care has been bypass surgery. Although such surgery may be associated with significant morbidity, the resulting long-term amputation-free survival rates are generally good. In recent years there has been a trend towards treating infra-geniculate disease with angioplasty, on the grounds that it is associated with less morbidity than surgery. However, this change in practice is not evidence-based, and serious concerns remain about the durability of angioplasty in this anatomical area. A multicentre, randomised controlled trial with a full health economic analysis is required to address this. The primary endpoint should be amputation-free survival, with secondary endpoints including overall survival, health-related quality of life, healing of tissue loss, and relief of ischaemic pain.

## 4.2 Supervised exercise programmes for treating people with intermittent claudication

What is the clinical and cost effectiveness of supervised exercise programmes compared with unsupervised exercise for treating people with intermittent claudication, taking into account the effects on long-term outcomes and continuing levels of exercise?

#### Why this is important

Research has shown that taking part in exercise and physical activity can lead to improvements in symptoms in the short term for people with intermittent claudication. However, the benefits of exercise are quickly lost if it is not frequent and regular. Supervised exercise programmes have been shown to produce superior results when compared with advice to exercise (unsupervised) in the short term, but they are more expensive, and there is a lack of robust evidence on long-term effectiveness. A community-based randomised controlled trial is required to compare the long-term clinical and cost effectiveness of a supervised exercise programme and unsupervised exercise. The trial should enrol people with peripheral arterial disease-related claudication, but exclude those with previous endovascular or surgical interventions. The primary outcome measure should be maximal walking distance, with secondary outcome measures including quality of life, function, levels of uptake of exercise programmes and long-term engagement in physical activity.

### 4.3 Patient attitudes and beliefs about peripheral arterial disease

What is the effect of people's attitudes and beliefs about their peripheral arterial disease on the management and outcome of their condition?

#### Why this is important

The evidence reviewed suggested that, among people with peripheral arterial disease, there is a lack of understanding of the causes of the disease, a lack of belief that lifestyle interventions will have a positive impact on disease outcomes, and unrealistic expectations of the outcome of surgical interventions. Much of the research has been conducted on the subpopulation of people with peripheral arterial disease who have been referred for surgical intervention, but little evidence is available for the majority of people diagnosed with peripheral arterial disease in a primary care setting. Research is required to further investigate attitudes and beliefs in relation to peripheral arterial disease, interventions that might influence these and how these may have an impact on behavioural changes in relation to risk factors for peripheral arterial disease, attitudes to intervention and clinical outcomes.

## 4.4 Primary versus secondary stenting for treating people with critical limb ischaemia caused by disease of the infra-geniculate arteries

What is the clinical and cost effectiveness of selective stent placement compared with angioplasty plus primary stent placement for treating people with critical limb ischaemia caused by disease of the infra-geniculate arteries?

#### Why this is important

Studies comparing angioplasty plus selective stent placement with primary stent placement have been limited to the aorto-iliac and femoro-popliteal segment. There is also a significant group of people with critical ischaemia caused by disease of the infra-geniculate vessels in which there is a potential for endovascular treatment. Infra-geniculate disease is more complex to treat by endovascular means, and the risks and benefits of different treatment options may differ from those for the more proximal vessels. A multicentre, randomised controlled trial with a full health economic analysis is required to address the optimum policy as regards the choice of method for angioplasty and stent placement for the infra-geniculate arteries. The primary endpoint should be amputation-free survival, with secondary endpoints including overall survival, re-intervention rates, health-related quality of life, healing of tissue loss, and relief of ischaemic pain.

## 4.5 Chemical sympathectomy for managing critical limb ischaemic pain

What is the clinical and cost effectiveness of chemical sympathectomy in comparison with other methods of pain control for managing critical limb ischaemic pain?

#### Why this is important

Approximately 1 in 5 people with critical limb ischaemia cannot be offered procedures to improve the blood supply to their leg because of either the pattern of their disease or other comorbidities. In this group the therapeutic options are pain control or primary amputation. Chemical lumbar sympathectomy, which involves the destruction of the lumbar sympathetic chain (usually the L2 and L3 ganglia), has been suggested to reduce pain and improve wound healing, and may prevent amputation in some patients. Initially achieved surgically, it is now most commonly performed using chemical agents such as phenol to destroy the lumbar sympathetic chain. Despite having been used for over 60 years, the role of chemical lumbar sympathectomy remains unclear. Improvement in skin blood flow and modification of pain perception control have been demonstrated, and this has prompted the use of chemical lumbar sympathectomy for treating a range of conditions such as regional pain syndrome, vasospastic conditions and critical limb ischaemia. However, in critical limb ischaemia the use of chemical lumbar sympathectomy varies widely between units in England, the mode of action and indications are unclear, and there is currently no randomised controlled trial evidence demonstrating its clinical value. Therefore a randomised control trial comparing chemical lumbar sympathectomy with other methods of pain relief is recommended.

## 5 Other versions of this guideline

## 5.1 Full guideline

The full guideline <u>lower limb peripheral arterial disease</u>: <u>diagnosis and management</u>, contains details of the methods and evidence used to develop the guideline. It is published by the National Clinical Guideline Centre.

## 5.2 NICE pathway

The recommendations from this guideline have been incorporated into a <u>NICE pathway</u>.

## 5.3 Information for the public

NICE has produced information for the public explaining this guideline.

We encourage NHS and voluntary sector organisations to use text from this information in their own materials about peripheral arterial disease.

## 6 Related NICE guidance

#### General

- Patient experience in adult NHS services (2012) NICE guideline CG138
- Opioids in palliative care (2012) NICE guideline CG140
- Medicines adherence (2009) NICE guideline CG76

#### Peripheral arterial disease

- <u>Percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease</u> (2012) NICE interventional procedure guidance 433
- <u>Cilostazol, naftidrofyryl oxalate, pentoxifylline and inositol nicotinate for the treatment of intermittent claudication in people with peripheral arterial disease</u> (2011) NICE technology appraisal guidance 223
- Endovascular stent-grafting for popliteal aneurysms (2011) NICE interventional procedure guidance 390
- Percutaneous atherectomy of femoro-politeal arterial lesions with plaque incision devices (2010) NICE interventional procedure guidance 380
- <u>Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin</u> (2008) NICE technology appraisal guidance 159

#### **Smoking cessation**

- Smoking cessation services (2008) NICE guideline PH10
- Preventing the uptake of smoking by children and young people (2008) NICE guideline PH14
- Varenicline for smoking cessation (2007) NICE technology appraisal guidance 123
- Brief interventions and referral for smoking cessation in primary care and other settings
   (2006) NICE guideline PH1

#### Diet, weight management and exercise

Prevention of cardiovascular disease (2010) NICE guideline PH25

- Physical activity and the environment (2008) NICE guideline PH8
- Promoting physical activity in the workplace (2008) NICE guideline PH13
- Obesity (2006) NICE guideline CG43
- Four commonly used methods to increase physical activity (2006) NICE guideline PH2

#### Lipid modification and statin therapy

- Lipid modification (2008) NICE guideline CG67
- Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia (2007) NICE technology appraisal guidance 132
- <u>Statins for the prevention of cardiovascular events</u> (2006) NICE technology appraisal guidance
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#### Prevention, diagnosis and management of diabetes

- Type 2 diabetes in adults (2015) NICE guideline NG28
- Type 1 diabetes in adults (2015) NICE guideline NG17
- <u>Diabetic foot problems</u> (2015) NICE guideline NG19
- Preventing type 2 diabetes: population and community-level interventions in high-risk groups and the general population (2011) NICE guideline PH35

#### Prevention, diagnosis and management of high blood pressure

Hypertension (2011) NICE guideline CG127

#### Antiplatelet therapy

• <u>Clopidogrel and modified release dipyridamole in the prevention of occlusive vascular events</u> (2010) NICE technology appraisal guidance 210

## 7 Updating the guideline

NICE guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations. Please see our website for information about updating the guideline.

## Appendix A: The Guideline Development Group, National Collaborating Centre and NICE project team

## Guideline Development Group

#### Jonathan Michaels (Chair)

Professor of Vascular Surgery, University of Sheffield

#### **Barry Attwood**

Patient and carer member

#### **Andrew Beech**

Chief Vascular Scientist, Nottingham University Hospital

#### **Andrew Bradbury**

Professor of Vascular Surgery, University of Birmingham

#### **Duncan Ettles**

Consultant Vascular Interventional Radiologist, Hull Royal Infirmary

#### **Martin Fox**

Vascular Specialist Podiatrist, Pennine Acute Hospitals Trust, Manchester

#### Michael Flynn

Consultant Physician in General Medicine, Kent and Canterbury Hospital

#### **Ammy Lam**

Principal Clinical Pharmacist, Barts and the London NHS Trust

#### Peter Maufe

Patient and carer member

#### **Ricky Mullis**

Physiotherapist and Senior Research Associate, University of Cambridge

#### **Anita Sharma**

General Practitioner, South Chadderton Health Centre, Oldham

#### Manohar Sharma (co-opted member)

Consultant in Pain Medicine and Anaesthesia, The Walton Centre for Neurology and Neurosurgery NHS Trust, Liverpool

#### Cliff Shearman

Professor of Vascular Surgery/Consultant Vascular Surgeon, University of Southampton

#### Hazel Trender

Senior Vascular Nurse Specialist, Northern General Hospital, Sheffield

#### Raman Uberoi

Consultant Interventional Radiologist, John Radcliff Hospital, Oxford

#### National Clinical Guideline Centre

#### Sarah Bermingham

Health Economist

#### Jill Cobb

Information Scientist

#### **Bernard Higgins**

**Clinical Director** 

#### Kate Kelley

Associate Director (from February 2011 until September 2011)

#### Taryn Krause

Senior Project Manager (until November 2010)

#### Jennifer Layden

Senior Project Manager (from November 2010)

#### Rachel O'Mahony

Senior Research Fellow (from April 2012)

#### Jill Parnham

Operations Director (until March 2011)

#### Laura Sawyer

Senior Health Economist (until January 2012)

#### Katrina Sparrow

Senior Research Fellow (until April 2012)

## NICE project team

#### Philip Alderson

Associate Director

#### Claire Turner

**Guideline Commissioning Manager** 

#### **Anthony Gildea**

**Guideline Coordinator** 

#### Nichole Taske

Technical Lead

#### Jasdeep Hayre

Health Economist

#### Rachael Paterson, Lyn Knott

**Editors** 

## Changes after publication

December 2015: Related NICE guidance section amended to refer to updated NICE guideline on type 2 diabetes in adults.

August 2015: Changes to related NICE guidance section following publication of updated NICE guidelines on <u>type 1 diabetes in adults</u> and <u>diabetic foot problems</u> (references to CG119, CG15, CG10 and TA60 have been removed because these have been updated).

November 2012: Minor maintenance.

## About this guideline

NICE guidelines are recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales.

The guideline was developed by the National Clinical Guideline Centre, which is based at the Royal College of Physicians. The Collaborating Centre worked with a group of healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, who reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

The methods and processes for developing NICE guidelines are described in the guidelines manual.

The recommendations from this guideline have been incorporated into a <u>NICE pathway</u>. We have produced <u>information for the public</u> explaining this guideline. Tools to help you put the guideline into practice and information about the evidence it is based on are also <u>available</u>.

#### Your responsibility

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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