NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

The IN.PACT drug-coated balloon for femoro-popliteal peripheral arterial disease

1 Technology

1.1 Description of the technology

The IN.PACT drug-coated balloon (Medtronic) is an over-the-wire angioplasty catheter and drug delivery system for treating people with femoro-popliteal peripheral arterial disease (PAD). The inflated balloon stretches and widens the narrowed vessel lumen by percutaneous transluminal angioplasty (PTA), leading to an increase in distal blood flow. The outer surface of the polyamide balloon is coated with paclitaxel at a dose of 3.5 µg/mm2, combined with a urea carrier which is delivered into the vessel wall at the time of balloon inflation. Paclitaxel reduces intimal smooth muscle cell proliferation that may subsequently lead to restenosis (recurrence of vessel narrowing).

The IN.PACT device has a dual-lumen shaft, one lumen for the passage of the guidewire, and the other to allow contrast medium diluted with saline to inflate and deflate the balloon. Two radiopaque markers identify the working length of the balloon to aid the accurate positioning of the device across the target lesion during X-ray fluoroscopy. The vessel may be pre-dilated with a conventional PTA balloon to a diameter 1mm less than the IN.PACT drug-coated balloon. Once positioned, the drug-coated balloon is inflated to the appropriate pressure and remains inflated for 1 minute to allow optimal drug delivery. The IN.PACT drug-coated balloon is designed for a single inflation only, after which it is deflated and withdrawn. More than 1 IN.PACT devices may be used in the same patient for cases with long or multiple lesions..<>

IN.PACT is available in a variety of balloon sizes and in 2 versions, depending on the diameter of the guidewire used: the IN.PACT Admiral is compatible with a 0.035” guidewire and the IN.PACT Pacific is compatible with a 0.018” guidewire.

1.2 Regulatory status

The IN.PACT (Paclitaxel-eluting PTA Balloon Catheter) drug-coated balloon received a CE mark in March 2009 for percutaneous transluminal angioplasty in patients with obstructive disease of the peripheral arteries. IN.PACT DCB received a CE mark in January 2015 for in-stent restenosis in patients with peripheral artery disease, as an expanded indication.

IN.PACT is contraindicated for use in the coronary arteries or cerebrovascular arteries, in lesions that cannot be crossed with a guidewire, in pregnant or breast-feeding women and in patients with known allergies or hypersensitivities to paclitaxel.

1.3 Claimed benefits

The benefits to patients claimed by the company are:

- A significant improvement in primary patency
- A significant decrease in rates of repeat interventions
- An improvement in target lesion revascularisation
- A reduction in claudication symptoms and scores
- An improvement in quality of life and function.

The benefits to the healthcare system claimed by the company are:

- A reduction in hospitalisations
- Cost savings through the avoidance of complications and subsequent hospitalisation and re-intervention

1.4 Relevant diseases and conditions

Peripheral arterial disease (PAD), also known as peripheral vascular disease, is a common condition, in which a build-up of fatty deposits in the arteries (atheroma) encroaches on the lumen of the vessel and restricts blood supply to the tissues of the leg. The incidence of PAD increases with age. Population studies have found that about 20% of people aged over 60 years have some degree of PAD. The incidence is also high in people who smoke, and in those with diabetes and/or coronary artery disease.

Many people with PAD have no symptoms but some develop a painful ache in their legs when they walk, which gradually resolves after a few minutes of rest. The medical term for this symptom is "intermittent claudication". In most people with intermittent claudication, the symptoms remain stable, but approximately 20% will develop increasingly severe symptoms as atheromatous narrowing increases and vascular insufficiency may ultimately lead to the development of critical limb ischaemia.

1.5 Current management

Current treatment options for femoro-popliteal PAD include balloon percutaneous transluminal angioplasty (without drug coating), implantation of scaffolding devices called stents or surgical revascularization techniques (bypass surgery).

NICE guidance on peripheral arterial disease: diagnosis and management recommends that initial management should focus on preventative treatments and lifestyle changes to reduce symptoms and the risk of developing other forms of atheromatous cardiovascular disease. The management of people with intermittent claudication is described in section 1.5 of the guideline. People with intermittent claudication should be offered a supervised exercise programme: angioplasty can only be offered when exercise has not shown improvement, lifestyle changes have been reinforced and when suitability has been confirmed by imaging. Bypass surgery should only be offered to people with severe lifestyle-limiting intermittent claudication when angioplasty has been unsuccessful or is unsuitable, and in the presence of appropriate

patterns of vascular disease. People with critical limb ischaemia should be assessed by a vascular multidisciplinary team before angioplasty or bypass surgery is recommended. When angioplasty is indicated, NICE guidance recommends the use of stenting only as a bail-out undertaking.

The IN.PACT drug-coated balloon is intended to deliver paclitaxel to the vessel wall in order to reduce re-stenosis.

2 Reasons for developing guidance on IN.PACT for peripheral arterial disease

The committee considered that IN.PACT may offer benefits to patients and the health care system through a long-term reduction in symptoms of peripheral arterial disease and through a reduction in the need for re-intervention.

The committee noted that the BASIL 3 trial will provide evidence as to the effectiveness of drug coated balloons in treating people with critical limb ischaemia, and therefore concluded that the present evaluation should focus on people with intermittent claudication as the indication for invasive treatment.

3 Statement of the decision problem

	Scope issued by NICE	
Population	People with femoro-popliteal peripheral arterial disease undergoing revascularization for intermittent claudication	
Intervention	Percutaneous transluminal angioplasty (PTA) with IN.PACT drug coated balloon (Pacific or Admiral versions) (with or without bailout stenting)	
Comparator(s)	Percutaneous transluminal angioplasty (PTA) with a non-drug coated balloon (with or without bailout stenting)	
Outcomes	The outcome measures to consider include: • Intermittent claudication symptom severity (including scores) • Quality of life and functional capability • Rate of hospitalization • Target lesion revascularisation rates • Primary patency rates • Repeat intervention rates • Rates of vessel thrombosis • Angiographically determined late lumen loss • Device-related adverse events	
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	• people presenting with in-stent restenosis • people with restenosis or recurrence	
Special considerations, including those related to equality	PAD is more common in older people and men and people with diabetes. Diabetes is more common in people from certain ethnic groups and race is a protected characteristic under the Equalities Act. Some people with PAD may have symptoms severe enough to limit their mobility and may be considered disabled under the Equalities Act.	
Special considerations, specifically related to equality issues	The technology is contraindicated in pregnant or breast-feeding women	
	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	Yes
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No

4 Related NICE guidance

Published

- Cardiovascular disease: risk assessment and reduction, including lipid modification (2014; updated 2016) NICE guideline CG181
- Lutonix drug-coated balloon for peripheral arterial disease (2016) MedTech innovation briefing 72
- Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease (2014; updated 2016) NICE guideline CG181
- Peripheral arterial disease (2015) NICE clinical knowledge summary
- PROPATEN heparin-bonded vascular graft for peripheral arterial disease (2015) MedTech innovation briefing 42
- Spiral Flow peripheral vascular graft for treating peripheral arterial disease (2015) MedTech innovation briefing 34
- Symptoms of peripheral arterial disease: Ramipril (2015) NICE evidence summary 45
- Peripheral arterial disease: diagnosis and management (2012) NICE guideline CG147
- Cardiovascular disease prevention (2010) NICE guideline PH25

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- British Atherosclerosis Society
- British Society for Interventional Radiology
- British Society for Endovascular Therapy
- Royal College of Nurses

- Royal College of Physicians
- Royal College of Radiologists
- Royal College of Surgeons
- Royal College of Surgeons of Edinburgh
- Society of Vascular Nurses
- The Vascular Society of Great Britain and Ireland
- Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- British Atherosclerosis Society
- British Society for Interventional Radiology
- British Society for Endovascular Therapy
- Royal College of Nurses
- Royal College of Physicians
- Royal College of Radiologists
- Royal College of Surgeons
- Royal College of Surgeons of Edinburgh
- Society of Vascular Nurses
- The Vascular Society of Great Britain and Ireland

5.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- British Heart Foundation
- British Heart Foundation
- Cardiovascular Care Partnership (UK)
- Lindsay Leg Club Foundation
- Lindsay Leg Club Foundation
- The Circulation Foundation
- UK Health Forum (formerly National Heart Forum)
- Vascular Society of Great Britain and Ireland