NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

SeQuent Please Neo balloon catheter for in-stent coronary restenosis

This is the scope for the update of NICE medical technologies guidance 1: SeQuent Please Neo balloon catheter for in-stent coronary restenosis. NICE reviewed this guidance and published the review decision in February 2017. The guidance is being updated using the accelerated update process described in the programme process guide.

1 Technology

SeQuent Please Neo (B Braun Medical) is a balloon catheter for percutaneous transluminal coronary angioplasty. The balloon is coated with the antimitotic drug paclitaxel, with the aim of reducing restenosis.

The balloon section of the catheter is coated with paclitaxel at a dose of 3 microgram/mm^2. When the balloon is expanded, paclitaxel is released into the vessel wall. Using paclitaxel reduces smooth muscle cell proliferation that can give rise to restenosis and recurrence of symptoms. The aim of targeted delivery is to achieve a high local concentration of drug in the vessel wall with minimal systemic release. The balloon catheter is also coated in iopromide, an X-ray contrast medium which aims to improve the solubility and transfer of paclitaxel to the vessel wall. After treatment, antiplatelet therapy with clopidogrel is recommended for 3 months in addition to aspirin to reduce the risk of thrombosis.

The cost of a SeQuent Please Neo balloon catheter is approximately £450–650. The cost of SeQuent Please Neo balloon catheter may vary because of differences in purchasing contracts.

1.1 Description of the technology

1.2 Regulatory status

The SeQuent Please Neo received a CE mark in 2015 for in-stent restenosis and is the successor to the technology recommended in MTG1.

Claimed benefits

The benefits to patients and to the health care system from the previous evaluation:

- Reduction in the rate of restenosis following treatment with SeQuent Please Neo in comparison with drug-eluting stents. This means that there is potential to reduce the costs associated with retreatment and recurrence of angina symptoms, as well as the duration of the antiplatelet therapy.

- If re-intervention is required, the company claims that there would be a wider range of treatment strategies available after treatment with SeQuent Please Neo, compared with stenting, because of the absence of an underlying metallic scaffold.

1.4 Relevant diseases and conditions

The SeQuent Please Neo is intended for use in restenosis after primary intervention.

In the UK, there are an estimated 2.3 million people living with CHD and around 2 million people affected by angina (the most common symptom of CHD). CHD generally affects more men than women, although from the age of 50 the chances of developing the condition are similar for both sexes.

A coronary angioplasty is one of the most common types of treatment for heart disease. Around 75,000 procedures are performed in England each year. Coronary angioplasties are most commonly performed in people aged 65 or older, as they are more likely to have CHD. If further narrowing of the target vessel occurs after intervention this is known as restenosis, in-stent restenosis in clinical practice is currently higher than 10%.

1.5 Current management

The most relevant NICE pathway is stable angina and is unchanged since the original guidance was published. The pathway includes MTG1 and is based on CG126 which was updated in August 2016.

Guidance on the use of drug eluting stents for coronary artery disease (TA152) was published in 2008.

2 Statement of the decision problem

	Scope issued by NICE	
Population	People with restenosis	
Intervention	SeQuent Please Neo iopromide/paclitaxel-eluting balloon catheter for percutaneous transluminal coronary angioplasty	
Comparator(s)	Repeat balloon angioplasty, repeat stenting, cutting balloon angioplasty, directional coronary atherectomy, rotational coronary atherectomy, brachytherapy and drug-eluting stents.	
Outcomes	The outcome measures to consider include: • target vessel revascularisation • late lumen loss • recurrence of angina • quality of life • successful device placement • death • 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	• Patients with complex coronary disease (for example, left main stem lesions, branch lesions and vessel bifurcations) or in situations where standard stent use is undesirable (for example, in calcified vessels or tortuous anatomy).	
Special considerations, including those related to equality	No special considerations	
Special considerations, specifically related to equality issues	None	
	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?	No*
	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*
	* Delete as appropriate, if yes please provide further details here:	

3 Related NICE guidance

Published

- Stable angina: management (2011) NICE guideline CG126
- Acute heart failure: diagnosis and management in adults (2016) NICE quality standard 103
- Bioresorbable stent implantation for treating coronary artery disease (2014) NICE interventional procedures guidance 492
- Prasugrel with percutaneous coronary intervention for treating acute coronary syndromes (2014) NICE technology appraisal guidance 317
- Stable angina (2012) NICE Quality Standard 21
- Percutaneous laser coronary angioplasty (2011) NICE interventional procedures guidance 378
- SeQuent Please Neo balloon catheter for in-stent coronary restenosis (2010) NICE med tech guidance 1
- Clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events (2010) NICE technology appraisal guidance 210
- Prasugrel for the treatment of acute coronary syndromes with percutaneous coronary intervention. (2009) NICE technology appraisal guidance 182
- Drug-eluting stents for the treatment of coronary artery disease (part review of NICE technology appraisal guidance 71). (2008) NICE technology appraisal guidance 152
- Totally endoscopic robotically assisted coronary artery bypass grafting (2005) NICE interventional procedures guidance 128
- Balloon angioplasty with or without stenting for coarctation or recoarctation of the aorta in adults and children (2004) NICE interventional procedures guidance 74
- Guidance on the use of coronary artery stents. (2003) NICE technology appraisal guidance 71
- HeartFlow FFRct for the estimation of fractional flow reserve from coronary CT angiography (2017) NICE med tech guidance 32.