NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Medical technology guidance

SCOPE

Pipeline embolisation device for the treatment of complex intracranial aneurysms

1 Technology

1.1 *Description of the technology*

The Pipeline embolisation device is a self-expanding blood flow diverter that is placed across the neck of an intracranial aneurysm. Once in place, the device provides a scaffold for endothelial growth and the achievement of a biological seal. While blood flow through the parent vessel is maintained, flow within the aneurysm sac is disrupted, leading to stagnation and eventual thrombosis.

Multiple devices can be deployed within each other and/or in sequence to increase the overall length of the construct or to increase the amount of metal surface coverage over a particular segment.

The Pipeline embolisation device is indicated for use in patients with complex intracranial aneurysms, specifically large and giant, wide necked and fusiform aneurysms. It may be used as an alternative to coiling, most commonly stent-assisted coiling particularly in patients for whom standard coiling and/or stenting is unsuitable or for whom previous coiling/clipping procedures have failed.

1.2 *Regulatory status*

The Pipeline embolisation device received a CE mark in June 2008 for endovascular embolisation of aneurysms.

1.3 *Claimed benefits*

The benefits to patients claimed by the manufacturer are:

- A higher rate of complete, permanent occlusion of the large/giant intracranial aneurysm compared with coiling and stent-assisted coiling, leading to reduced rates of retreatment and decreasing the risk of haemorrhage.
- Increased accessibility to treatment for patients with complex intracranial aneurysms. The Pipeline embolisation device offers a new treatment option for patients with complex intracranial aneurysms who are not suitable for treatment by stent-assisted coiling or surgery, or for whom previous interventions have failed.
- Patients may experience a resolution of the mass effect.
- Increased long term vessel patency.

The benefits to the health system claimed by the manufacturer are:

- The high rate of complete, permanent occlusion of the target aneurysm with the Pipeline embolisation device may lead to a reduced need for retreatment and an overall decrease in NHS resource utilisation.

1.4 *Relevant diseases and conditions*

The Pipeline embolisation device is intended for use in patients with complex intracranial aneurysms, specifically those that are large and giant, wide necked and fusiform.

It is estimated that between 1 and 6% of the population in England has an intracranial aneurysm. Intracranial aneurysms, especially those that are large or giant, may present with mass effect leading to local compressive symptoms or rupture leading to subarachnoid haemorrhage. The estimated risk of rupture of all intracranial aneurysms is approximately 0.5% -10% per annum. Subarachnoid haemorrhage has a poor prognosis: approximately 10-15% of people die within 24 hours and a further 15-25% more die within four weeks.

Overall, an estimated 1,400 people die each year in the UK as a result of a ruptured intracranial aneurysm leading to subarachnoid haemorrhage. Of those patients who survive a subarachnoid haemorrhage, approximately 25-30% have a persisting neurological deficit.

1.5 *Current management*

Current treatment options for patients with complex intracranial aneurysms include coiling, often with concomitant use of stent placement, neurosurgical clipping requiring craniotomy (+/- bypass procedures), parent vessel sacrifice and conservative management.

2 Reasons for developing guidance on Pipeline embolisation device for the treatment of complex intracranial aneurysms

The Committee recognised that the Pipeline embolisation device may be of particular benefit in patients with complex intracranial aneurysms for whom standard coiling and stenting is either unsuitable or has previously failed. Standard surgical treatment for these patients is either impossible or attended by a very high risk of stroke or death while conservative treatment is associated with poor prognosis and a high risk of rupture and death. The Pipeline embolisation device therefore represents a potentially promising advance in the treatment of patients with large and giant, wide-necked and fusiform aneurysms in whom the prognosis is poor and current treatment options are limited.

The published evidence indicates the Pipeline embolisation device to be efficacious in achieving blood flow diversion, thrombosis of the aneurysm and resolution of symptoms associated with intracranial aneurysms.

The Committee concluded that there may be important differences between different blood flow diverter devices with regard to their clinical outcomes and cost impact.

3 Statement of the decision problem

	Scope issued by NICE
Population	Patients with complex intracranial aneurysms, specifically large / giant, wide necked and fusiform aneurysms.
Intervention	Pipeline embolisation device
Comparator(s)	Stent-assisted coiling Parent vessel occlusion Neurosurgical techniques Conservative management (see also 'Cost analysis' below)
Outcomes	The outcome measures to consider include: • successful device deployment • succesful occlusion of the aneurysm, with and without preservation of flow through the parent vessel, • size of collective aneurysm-thrombus mass, • resolution of symptoms (i.e. headache, diplopia, nystagmus or other neurological dysfunction), relief of pain and quality of life outcomes, • resource use outcomes for example re-admission rates, re-interventions and duration of hospital stay • stroke (all causes, but specifically when caused by blood clot or bleed related to the interventional procedure) • delayed parent vessel occlusion, • subarachnoid haemorrhage and / or other major bleeding events requiring hospitalisation and/or transfusion or active treatment • neurovascular death • device-related adverse events
Cost analysis	Three cost analyses to be undertaken. <u>Analysis 1</u> Population: Patients with complex intracranial aneurysms for whom stent-assisted coiling is considered feasible (de novo or repeat treatment). Intervention: Pipeline embolisation device Comparator: Percutaneous interventional techniques including stent-assisted coiling and parent vessel occlusion <u>Analysis 2</u> Population: Patients with complex intracranial aneurysms for whom stent-

	assisted coiling is not considered feasible (de novo or repeat treatment). Intervention: Pipeline embolisation device Comparator: Neurosurgical techniques (including bypass) Analysis 3 Population: Patients with complex intracranial aneurysms for whom stent-assisted coiling and neurosurgical techniques are not considered feasible (de novo or repeat treatment). Intervention: Pipeline embolisation device Comparator: Conservative treatment. Costs will be considered from an NHS and Personal Social Services perspective. Both the analyses should take into account hospital care (surgical time and recovery), and the long term management of the aneurysm including drug costs, for example, antiplatelet therapy. Additional training required to use the device should be accounted for. Adverse events and complications relating to the use of the device (including re-intervention) and treatment required for these complications should also be considered (for example, the costs associated with social care if the patient has a stroke). The time horizon for the economic evaluation should be based on the appropriate time period over which costs and benefits can reasonably be expected to be experienced given the chronic nature of the condition. The sensitivity analysis should address uncertainties in the model parameters, which should include scenarios in which different numbers and combinations of devices are required.
Subgroups to be considered	None identified.
Special considerations, including issues related to equity or equality	The natural history of the disease should be considered and presented.

4 External organisations

4.1 *Professional organisations*

4.1.1 Specialist societies contacted for expert advice

British Society of Neuroradiologists

4.1.2 Specialist societies invited to comment on the draft scope

British Society of Neuroradiologists

UK Neurointerventional group

Society of British Neurosurgeons

Royal College of Radiologists

4.2 *Patient organisations*

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

Brain and Spinal Injury Charity (BASIC)

Brain and Spine Foundation

CORDA - The Coronary Artery Disease Research Association

Different Strokes

Headway - the Brain Injury Association

National Heart Forum (UK)

Neurological Alliance

Neurosupport

Stroke Association

UK Acquired Brain Injury Forum

Vascular Society