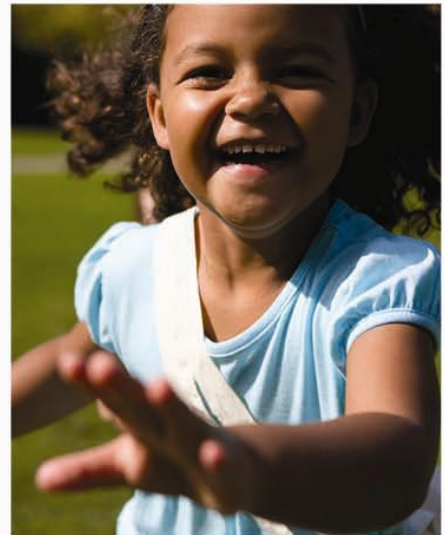


**Clinical Commissioning  
Policy Statement: Flow  
Diverting Devices for  
Intracranial Aneurysms**

**April 2013**

**Reference : NHSCB/D03/PS/a**



# **NHS Commissioning Board Clinical Commissioning Policy Statement: Flow Diverting Devices for Intracranial Aneurysms**

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**Prepared by the NHS Commissioning Board Clinical Reference Group for**

**Adult Neurosurgery**

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**POLICY STATEMENT:**  
**Flow Diverting Devices For**  
**Intracranial Aneurysms**

**Policy Ref:**  
**NHSCB/D03/PS/a**

<b>Treatment:</b>	Flow diverting embolization devices: Pipeline Embolisation Device (PED) : Covidien <sup>1</sup> SILK artery reconstruction device: Balt Extrusion <sup>2</sup>
<b>For:</b>	<b>Unruptured intracranial aneurysms</b>
<b>Background:</b>	<p>Intracranial aneurysms are dilated blood vessels within the skull. Their rupture causes a subarachnoid haemorrhage, which can cause death or serious disability.</p> <p>The majority of unruptured aneurysms are diagnosed incidentally. The standard approach to reduce the risk of future rupture involves open surgery to clip the aneurysm's neck, or endovascular coil embolisation, with or without stenting.</p> <p>The Flow Diverting or Pipeline Embolisation Device (PED) is a self-expanding blood flow diverter that is placed across the neck of an intracranial aneurysm. It is intended for use in patients with complex intracranial aneurysms, specifically those that are large or giant, wide necked or fusiform. 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.</p> <p>The SILK artery reconstruction device is not a direct comparator to PED but is being used to manage intracranial aneurysms in some patients. The SILK device is currently under review by the MHRA and has been recalled by the manufacturers due to concerns about its safety. The SILK device should not be used without embolisation coils.<sup>2</sup></p> <p>The National Institute for Health and Clinical Excellence (NICE) Medical Technologies Guidance (MTG)<sup>3</sup> states that the use of PED in the NHS is supported by the current evidence when it is used in patients with complex giant or large intracranial aneurysms which are unsuitable for surgery and being considered for stenting, and where large numbers of coils would be needed during stent-assisted coiling.</p> <p>NICE recognised that there are a small number of patients (an estimated 60 patients per year in the UK) for whom PED</p>

offers the only possible means of treatment.<sup>3</sup>

Data from the UKNG Flow Diverter Registry reported 77 cases in a 12 month period in 2011/12.<sup>4</sup>

The Adult Neurosurgery CRG has identified the types of unruptured intracranial aneurysm that should be supported by the NHS CB. They have also identified a group of patients with ruptured aneurysms who may benefit from a flow diverter.

These are a small subgroup of patients with rare, recently ruptured 'blood blister' aneurysms. Although there is no evidence that flow diverters have advantages over other treatments in these cases, patients are at high risk of early rehaemorrhage, within a short time frame, associated with a high mortality rate. These types of aneurysms are difficult to repair surgically or with conventional coils and stents as the vessel is extremely fragile and consequently there is a high risk of procedural rupture.<sup>5, 7</sup>

A recent evidence review commissioned to support this policy<sup>6</sup> identified two uncontrolled prospective studies and one retrospective uncontrolled study in progress, although the results are unlikely to be available for some time.

NICE recommends that clinicians should submit details of all patients being treated with PED, or other flow diverting stents, to the UK Flow Diverter Registry, to increase the evidence base and guide future use of this technology.

**Commissioning position:**

The NHS Commissioning Board will commission the use of a flow diverter where the patient:

- has one of the following conditions:
  - Large or giant unruptured intradural saccular aneurysm of anterior circulation
  - Large or giant unruptured intradural fusiform aneurysm of anterior circulation
  - Large or giant unruptured intradural aneurysm of the posterior circulation
  - Symptomatic unruptured extradural aneurysm (including cavernous carotid)
  - Recently ruptured 'blood blister' aneurysm
- is considered fit for general anaesthesia.
- has a contra-indication to both neurosurgery and endovascular coiling (with or without stents), or these

are not feasible or have failed.

- is not expected to need more than two flow diverter devices inserted.
- will be under shared care with a vascular neurosurgeon and the procedure will be carried out in a specialist unit.
- has documented case discussion at a multidisciplinary team (MDT) meeting, including interventional neuroradiology and vascular neurosurgery.

A careful risk / benefit assessment of the use of this intervention in asymptomatic disease has been carried out. The patient understands that the treatment remains under evaluation and this is clearly documented.

The patient understands that the treatment remains under evaluation and that the standard treatment is usually conservative / medical. They are also aware that symptoms may persist following flow diverter treatment. They should be aware of known complications from existing research and this is clearly documented. Patients should also be aware of the need for regular and long term monitoring and follow up.

External peer review of case selection should be sought:

- By inexperienced operators (<10 cases/individual or <20 cases/centre)
- If there is uncertainty, or the MDT deems the case controversial, even in experienced centres

Requests for funding should be made via a prior approval request form specific to this policy.

Where treatment is needed for recently ruptured 'blood blister' aneurysms as an emergency, this must be justified and funding requests **MUST** be made within 7 days of treatment in order to be approved. The decision to proceed is based on local experience and expertise. This is understood by the patient and relatives and this is clearly documented.

In view of the limitations to the evidence base, commissioners will monitor the uptake of this treatment closely. Information on procedural events and outcomes should be collected and made available on request.

Clinicians should also submit details of all patients treated to the UK Flow Diverter Registry, to increase the

evidence base and guide future use of this technology.

**Effective from:** 1 April 2013

**Evidence Summary:** “Evidence from one systematic review and three further small prospective multi-centre studies suggests that PED is effective among patients with aneurysms that were wide-necked, fusiform, had unfavourable dome/neck ratios, or had failed previous therapy.

A cost comparison in the NHS suggests that PED is likely to be clinically and cost effective for the prophylactic treatment of unruptured intracranial aneurysms where otherwise 32 or more coils would be needed, but not cost-effective compared with stent-assisted coiling (using one stent) if 31 coils or fewer are used, or with neurosurgical clipping, endovascular parent vessel occlusion, neurosurgical parent vessel occlusion or conservative management for patients in whom those other options were feasible.

The recommendation of the NICE MTG<sup>3</sup> on the use of PED is that it should be confined to patients in whom both neurosurgery and endovascular coiling are contra-indicated, not feasible or failed, or where otherwise 32 or more coils would be needed.”<sup>6</sup>

The total cost of treatment using two PEDs is greater than that of stent-assisted coiling (using one stent) if 31 coils or fewer are used, but the Pipeline embolisation device is less costly if 32 or more coils are needed. The cost saving associated with PED compared with stent-assisted coiling with 32 coils was estimated to be £492 (total costs of £30,346 and £30,838 respectively).<sup>3</sup>

**Equality Impact:** The NHS CB has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

**Responsible CRG:** Adult Neurosurgery CRG

**Date approved by NHSCB Board:** April 2013

**Policy review date:** 2013/4

**Version:** 1

**Supersedes:** N/A

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**Change Notice for Published Specifications and Products  
developed by Clinical Reference Groups (CRG)**

**Amendment to the Published Products**

**Product Name**

Flow Diverting Devices for Intracranial Aneurysms

**Ref No**

D03/PS/a

**CRG Lead**

Adult Neurosurgery

**Description of changes required**

Describe what was stated in original document	Describe new text in the document	Section/Paragraph to which changes apply	Describe why document change required	Changes made by	Date change made
D03/PS/d	D03/PS/a	Title page and throughout document	To standardise naming and coding of products	Programme of Care Director for Trauma	September 2013