Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)
Welsh Health Specialised Services Committee (WHSSC)

# Specialised Services Policy:
# CP101
# Pipeline Embolisation Devices for Intracranial Aneurysms (Complex Giant or Large Intracranial Aneurysms)

| | |
|---|---|
| **Document Author:** | Assistant Director of Planning |
| **Executive Lead:** | Director of Planning |
| **Approved by:** | Management Group |
| **Issue Date:** | 1 July 2015 |
| **Review Date:** | 2023 |
| **Document No:** | CP101 |

**Document History**

| **Revision History** | | | |
|---|---|---|---|
| Version No. | Revision date | Summary of Changes | Updated to version no.: |
| 0.1 | | New draft Clinical Access Policy | 0.1 |
| 0.2 | 21.05.15 | Transferred onto correct template<br>Revised in line with approved commissioning intentions for neuroradiology and feedback from consultation undertaken in August 2014 | 0.2 |
| 0.2 | 26.06.215 | Approved by Management Group | 1.0 |
| | | | |
| Date of next revision | | **June 2018** | |

| **Consultation** | | |
|---|---|---|
| Name | Date of Issue | Version Number |
| Members of WHSSC Neurosurgery CEEG | 21.05.15 | 0.2 |
| Members of WHSSC Neurological and Complex Conditions Programme Team | 21.05.15 | 0.2 |
| Medical Directors HBs | 21.05.15 | |
| Lead consultant interventional neuroradiologists – WCFT and NBT | 21.05.15 | 0.2 |
| Members of WHSSC Management Group | 26.06.15 | 0.2 |
| | | |
| | | |

| **Approvals** | | |
|---|---|---|
| Name | Date of Issue | Version No. |
| WHSSC Executive Board | 15.06.15 | 0.2 |
| Management Group | 26.06.15 | 1.0 |
| | | |

| **Distribution – *this document has been distributed to*** | | | |
|---|---|---|---|
| Name | By | Date of Issue | Version No. |
| | | | |
| | | | |
| | | | |
| | | | |

## Policy Statement

| | |
|---|---|
| **Background** | The **Pipeline Embolisation Device** (PED) is a type of flow diversion device. The **Flow Diversion Device** is a self-expanding blood flow diverter that is placed across the neck of an intracranial aneurysm. The evidence base for use is in patients with unruptured complex intracranial aneurysms that are large or giant, wide neck or fusiform.<br><br>**Intracranial aneurysms:** Dilated blood vessels within the skull. Their rupture causes a subarachnoid haemorrhage which can cause death or disability. The majority of unruptured aneurysms are diagnosed incidentally. The standard approach to reducing the risk of rupture involves endovascular coil embolisation with or without stenting or open surgery to clip the aneurysm neck. |
| **Summary of Access Criteria** | The Welsh Health Specialised Services Committee (WHSSC) will fund the use of pipeline embolisation devices where the patient has one of the following conditions:<br><br>- Large or giant unruptured intradural saccular aneurysm of anterior circulation;<br><br>- Large or giant unruptured intradural fusiform aneurysm of anterior circulation;<br><br>- Large or giant unruptured intradural aneurysm of posterior location;<br><br>- Symptomatic unruptured extradural aneurysm (including cavernous carotid);<br><br>- Recently ruptured 'blood blister' aneurysm.<br><br>**AND**<br>- Is considered fit for general anaesthesia;<br><br>- Has a recorded contra-indication to both neurosurgery and endovascular coiling (with or without stents), or these are not clinically feasible or have failed;<br><br>- Is not expected to need more than two |

| | |
|---|---|
| | flow diverter devices inserted;<br><br>- Will be under shared care with a vascular neurosurgeon and the procedure will be carried out in a specialist unit;<br><br>- Has documented case discussion at a multidisciplinary (MDT) team meeting including interventional radiology and vascular neurosurgery.<br><br>This policy does not apply to use of the SILK artery reconstruction device. |
| **Responsibilities** | Designated providers must comply with the commissioning intentions (annex iii), and ensure that patients are treated in accordance with the Policy. Providers are required to submit the data specified in annex i and ii to the WHSSC Information Team.<br><br>The referring clinician must use the Policy to advise patients of the treatment options and refer patients in line with the Policy. |

## Table of Contents

## 1. AIM

### 1.1 Introduction

The document is the commissioning policy for Pipeline Embolisation Devices for the treatment of complex intracranial aneurysms in Welsh patients. The policy applies to residents of all seven Health Boards in Wales and English residents with a Welsh GP.

The purpose of this document is to:

- Set out the circumstances under which patients will receive a pipeline embolisation device for the treatment of complex intracranial aneurysms;
- clarify the referral process; and
- define the criteria that patients must meet in order to recieve treatment.

The Policy also clarifies the funding arrangements for Pipeline Embolisation Devices.

### 1.2 Relationship with other Policies and Service Specifications

This document should be read in conjunction with the following documents:

- All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR).
- Commissioning Intentions for Neuroradiology (annex iii)

## 2. SCOPE

### 2.1 Definition

The **Pipeline Embolisation Device** (PED) is a type of flow diversion device. The **Flow Diversion Device** is a self-expanding blood flow diverter that is placed across the neck of an intracranial aneurysm. The evidence base for use is in patients with unruptured complex intracranial aneurysms that are large or giant, wide neck or fusiform.

It may also 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 procedures have failed.

The SILK artery reconstruction device is not a direct substitution to PED but has also been used to treat intracranial aneurysms. The SILK device is currently under review by the MHRA and has been recalled by the manufacturers due to concerns about safety. The SILK device is NOT approved for the treatment of Welsh patients.

**Intracranial aneurysms** are dilated blood vessels within the skull. Their rupture causes a subarachnoid haemorrhage which can cause death or disability. The majority of unruptured aneurysms are diagnosed incidentally. The standard approach to reducing the risk of rupture involves endovascular coil embolisation with or without stenting or open surgery to clip the aneurysm neck.

The National Institute for Health and Clinical Excellence (NICE) Medical Technologies Guidance (MTG) 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. NICE have also recognised that there are a small number of patients (an estimated 60 patients per year in the UK) for whom PED offers the only possible means of treatment.

The Adult Neurosurgery Clinical Reference Group has identified the types of unruptured intracranial aneurysm, and a small subgroup of patients with ruptured aneurysms, who may benefit from a pipeline embolisation device.

This latter subgroup consists 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. Such 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.

A recent evidence review commissioned to support the development of the NHS England clinical commissioning policy identified two uncontrolled prospective studies and one retrospective uncontrolled study in progress, although the results are unlikely to be available for some time.

WHSSC requires that clinicians should submit details of all patients being treated with flow diversion devices to the UK Flow Diverter Registry, in order to increase the evidence base and guide future use of this technology.

## 2.2 Codes

### ICD-10 Codes

| Code | Description |
|---|---|
| I67.1 | Cerebral aneurysm, nonruptured |

# 3. ACCESS CRITERIA

## 3.1 Criteria and Indications for Treatment

The criteria for treatment are shown below. These should be established through an assessment as specified in section 3.3:

- 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 posterior location;
- Symptomatic unruptured extradural aneurysm (including cavernous carotid);
- Recently ruptured 'blood blister' aneurysm.

**AND**

- Is considered fit for general anaesthesia;
- Has a recorded contra-indication to both neurosurgery and endovascular coiling (with or without stents), or these are not clinically 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 (MDT) team meeting including interventional radiology and vascular neurosurgery.

This policy does not apply to use of the SILK artery reconstruction device.

## 3.2 Exclusions

This policy does not apply to:

- Aneurysm types not specified by this policy;
- Ruptured or leaking aneurysms (other than those specified in section 3.1);
- Flow Diverters not specified in this policy

## 3.3 Treatment and referral Pathway

Patients with any of the diagnoses specified in section 3.1 should be referred to the designated neurosurgical unit:

- South, Mid and West Wales – University Hospital of Wales
- North Wales – Walton Centre

Patients with confirmed aneurysmal subarachnoid haemorrhage are admitted to the service within 24 hours of ictus for appropriate resuscitation, and are treated within 48 hours of ictus.

The management of each referral should be discussed and agreed by the neurovascular surgeon, interventional neuroradiologist and where appropriate the neurocritical care specialist. External peer review of case selection should be sought:

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

On assessment, the specialist unit/MDT must submit a request to the WHSSC IPFR Team for funding via prior approval.

## 3.4 Audit of Policy Application

Providers must supply audit data to assure WHSSC of the application of the Policy on a quarterly basis.

If the patient wishes to be referred to a provider out of the agreed pathway, an IPFR should be submitted.

## 3.5 Exceptions

If the patient does not meet the criteria for treatment, but the referring clinician believes that there are exceptional grounds for treatment, an Individual Patient Funding Request (IPFR) can be made to WHSSC under the *All Wales Policy for Making Decisions on Individual Patient Funding Requests (IPFR)*.

If the patient wishes to be referred to a provider out of the agreed pathway and the referring clinician believes that there are exceptional grounds for treatment at an alternative provider, an Individual Patient Funding Request (IPFR) can be made to WHSSC under the *All Wales Policy for Making Decisions on Individual Patient Funding Requests (IPFR)*.

Guidance on the IPFR process is available at www.whssc.wales.nhs.uk

## 3.6 Responsibilities

3.6.1 University Hospital of Wales, Walton Centre

Designated providers must comply with the commissioning intentions (annex iii), and ensure that patients are treated in accordance with the Policy. Providers are required to submit the data specified in annex i and annex ii to the WHSSC Information Team.

3.6.2 Referring Clinician

The referring clinician must use the Policy to advise patients of their treatment options and refer patients in accordance with the Policy.

If the patient meets the criteria but wants to be referred to a non-contract provider an IPFR request must be completed and sent to WHSSC for approval of funding before treatment commences.

If the patient does not meet the criteria but there is evidence of exceptionality, an IPFR request must be completed and sent to WHSSC for approval of funding before treatment commences.

# 4. PUTTING THINGS RIGHT: RAISING A CONCERN

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment

provided. The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern:

- When a patient or their representative is unhappy with the decision that the patient does not meet the criteria for treatment further information can be provided demonstrating exceptionality. The request will then be considered by the All Wales IPFR Panel.
- If the patient or their representative is not happy with the decision of the All Wales IPFR Panel the patient and/or their representative has a right to ask for this decision to be reviewed. The grounds for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated. The review should be undertaken, by the patient's Local Health Board;
- When a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to WHSSC.

## 5. EQUALITY IMPACT AND ASSESSMENT

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (welsh).

This policy has been subjected to an Equality Impact Assessment. The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

## Annex (i) Audit of Application of Policy

Providers must complete the following form and submit to the WHSSC Information Team.

| | | | |
|---|---|---|---|
| Patient NHS No: | | | |
| Patient is Welsh Resident | Post Code | | |
| Patient is English Resident registered with NHS Wales GP | GP Code | | |
| | | | |
| **Patient meets the following access criteria and indications for treatment:** | | **Yes** | **No** |
| Large or giant unruptured intradural saccular aneurysm of anterior circulation; **OR** | | | |
| Large or giant unruptured intradural fusiform aneurysm of anterior circulation; **OR** | | | |
| Large or giant unruptured intradural aneurysm of posterior location; **OR** | | | |
| Symptomatic unruptured extradural aneurysm (including cavernous carotid); **OR** | | | |
| Recently ruptured 'blood blister' aneurysm. | | | |
| **AND** | | | |
| Is considered fit for general anaesthesia; **AND** | | | |
| Has a recorded contra-indication to both neurosurgery and endovascular coiling (with or without stents), or these are not clinically feasible or have failed; **AND** | | | |
| Is not expected to need more than two flow diverter devices inserted; **AND** | | | |
| Will be under shared care with a vascular neurosurgeon and the procedure will be carried out in a specialist unit; **AND** | | | |
| Has documented case discussion at a multidisciplinary (MDT) team meeting including interventional radiology and vascular neurosurgery. | | | |
| The patient's disease is not in one of the excluded categories detailed in section 3.2. | | | |
| Patient assessment has been carried out as in section 3.3. | | | |
| Patient is eligible for funding based on the Policy requirements . | | | |

**Date patient starts treatment ……**

## Annex (ii) Clinical Outcomes and Quality Criteria

All treating centres are required to submit data of all patients treated to the UK Flow Diverter Registry.

**Clinical Outcomes**
A clinical audit will be required on an annual basis from providers which will include the following:

- In hospital mortality
- Post operative mortality up to 30 days
- Successful device placement (without death or ipsolateral stroke);
- Fatal/non-fatal peri-procedural stroke (any);
- Fatal/Non-fatal stroke (any);
- Bleeding (major, minor, any);
- Complete occlusion of the aneurysm and absence of parent vessel stenosis greater than 50% at 180 days;
- 12-month survival;
- Rankin score at 180-days follow-up.
- EQ-5D, SF-6D or similar
- Resources:
    - Total flow diversion devices used;
    - Average flow diversion devices used;
    - Post operative bed length of stay (ITU, HDU, ward).

Due to the low numbers of patients expected, audit data will be reviewed on an annual basis.

**Serious Incidents**
Deaths and serious adverse events must be reported in real time (48 hours following the event) directly to the Medical Director and Director of Nursing, WHSSC.

## Annex (iii) Commissioning Intentions for Neuroradiology

### Quality and clinical governance

i) Ensure service complies with the guidelines set out in Safe Neuroradiology 2012 (British Society of Neuro Radiologists, 2012), and the Standards for Providing a 24 hour Interventional Neuroradiology Service (Royal College of Radiologists, 2008).

ii) Ensure that the service undertakes a comprehensive rolling audit programme, and presents its audit and outcome data at an annual multi centre audit event.

iii) Ensure that the service complies with the *'National Clinical Guideline for Stroke',* i.e. all patients are treated within 48 hours of their aneurysmal subarachnoid haemorrhage.

### Access

iv) Ensure that patients with confirmed aneurysmal subarachnoid haemorrhage are admitted to the service within 24 hours of ictus for appropriate resuscitation, and are treated within 48 hours of ictus.

v) Ensure that the interventional neuroradiology service is available to patients 12 hours a day and 6 days a week, with matching neurovascular surgery cover to ensure that patients have access to the most clinically appropriate treatment to manage their condition.

vi) The service should have formalised arrangements with other centres in order to ensure timely treatment of patients with acute neurovascular disease when the service is not available for during periods of laboratory downtime.

vii) The management of each referral should be discussed and agreed by the neurovascular surgeon, interventional neuroradiologist and where appropriate the neurocritical care specialist

viii) Formal networks of care should be established between the Neurovascular Multi Disciplinary Team and the secondary care hospitals that receive patients with subarachnoid haemorrhage.

ix) The Neurovascular Multi Disciplinary Team should work with the networks to develop standard protocols for care of patients with neurovascular disease in secondary care hospitals, including initial assessment, diagnosis, management, referral, transfer to a neurovascular services and subsequent repatriation and rehabilitation.

**Staffing**

i) There should be a minimum of three interventional neuroradiologists with appropriate experience.
ii) An interventional neuroradiologist should be available for consultation on every working day and at other times by local arrangement.
iii) Neurosurgical and anaesthetic support should be available to match the provision of Interventional Neuroradiology.
iv) Interventional Neuroradiologists should attend Neurovascular MDT meetings, and Morbidity and Mortality meetings, with other colleagues as specified below.
v) The Neurovascular MDT should include:
    a. Neurosurgeons with training and expertise in the treatment of neurovascular conditions;
    b. Conventional and interventional neuro-radiologists,
    c. Neuroanaesthetists;
    d. Neurocritical care specialists;
    e. Specialist nurses with expertise in the management of patients with neuro-vascular conditions.

**Equipment**

vi) Departments should have exclusive access to high resolution digital angiographic equipment (biplane with a rotational 3D processing facility).
vii) A back-up angiographic room is also essential, as well as links with other centres to manage periods of laboratory downtime.
viii) Departments should have rapid access to:
    - multi-slice CT,
    - CT angiography and
    - CT perfusion
    - MR
    - MR angiography of the cervical and cerebral arteries is required.
ix) Departments should have:
    a. robust equipment replacement programs in place to ensure that equipment is fit for purpose.
    b. strategies to minimise downtime and risk to service during equipment replacement should be in place.