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Committee

Intra-arterial Adjunct Devices Adults and Young People (aged 16 and over)

Commissioning Policy: CP101

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COMMISSIONING POLICY:
 CP101, INTRA-ARTERIAL ADJUNCT DEVICES ADULTS AND YOUNG PEOPLE (AGED 16
 AND OVER)

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Description	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy
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Policy Statement

NHS Wales Joint Commissioning Committee (NWJCC) will commission Intra-arterial Adjunct Devices for adults and young people (aged 16 and over) for the treatment of complex intracranial aneurysms in accordance with the criteria outlined in this document.

In creating this document NWJCC has reviewed the requirements and standards of care that are expected to deliver this service.

Welsh Language

NWJCC is committed to treating the English and Welsh languages on the basis of equality, and endeavour to ensure commissioned services meet the requirements of the legislative framework for Welsh Language, including the [Welsh Language Act \(1993\)](#), the [Welsh Language \(Wales\) Measure 2011](#) and the [Welsh Language Standards \(No.7\) Regulations 2018](#).

Where a service is provided in a private facility or in a hospital outside of Wales, the provisions of the Welsh language standards do not directly apply but in recognition of its importance to the patient experience, the referring health board should ensure that wherever possible patients have access to their preferred language.

In order to facilitate this, NWJCC is committed to working closely with providers to ensure that in the absence of a Welsh speaker, written information will be offered and people have access to either a translator or 'Language-line' if requested. Where possible, links to local teams should be maintained during the period of care.

Decarbonisation

NWJCC is committed to taking assertive action to reducing the carbon footprint through mindful commissioning activities. Where possible and taking into account each individual patient's needs, services are provided closer to home, including via digital and virtual access, with a delivery chain for service provision and associated capital that reflects the NWJCC commitment

Disclaimer

NWJCC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this policy.

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the

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circumstances of the individual patient, in consultation with the patient and/or their carer or guardian, or Local Authority.

NWJCC disclaims any responsibility for damages arising out of the use or non-use of this policy.

1. Introduction

This policy has been developed as a Policy for the planning and delivery of Intra-arterial Adjunct Devices for adults and young people (aged 16 and over) for the treatment of intracranial aneurysms for people resident in Wales. This service will only be commissioned by the NHS Wales Joint Commissioning Committee (NWJCC) and applies to residents of all seven Health Boards in Wales.

1.1 Background

An intracranial aneurysm is a bulge in a blood vessel in the brain caused by a weakness in the blood vessel wall, usually where it branches. Most brain aneurysms only cause noticeable symptoms if they rupture. However, large aneurysms may cause local compression symptoms before they rupture, such as headache. Rupture of intracranial aneurysms causes subarachnoid haemorrhage and is associated with a very poor prognosis. About 10% of people die before reaching hospital and a further 50% die within 4 weeks. About 50% of people who survive a subarachnoid haemorrhage have a persistent neurological deficit¹.

The majority of unruptured aneurysms are diagnosed incidentally. The standard approach to reduce the risk of future rupture involves endovascular coil embolisation, with or without stenting. This is typically only done if the risk of a rupture is particularly high and outweighs the risk of conservative management as advised by the Multidisciplinary team (MDT).

A stent device may be an option for some people with intracranial aneurysms. A flow diverter is a type of braided stent. All intracranial stents are self-expanding and are placed across the neck of an intracranial aneurysm. While blood flow through the parent vessel is maintained via the device, flow within the aneurysm sac is disrupted, leading to stagnation and eventual thrombosis formation. The evidence base for use is in patients with unruptured/ruptured complex intracranial aneurysms, to prevent the aneurysm from rupturing or to stop a further bleed from an aneurysm that has already ruptured.

Any aneurysm that can be treated with stent assisted coiling is likely to be able to be treated with a flow diverter, therefore 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. A flow diverter can also be used as a second line to complete treatment in acute patients after they have recovered.

¹ <https://www.nice.org.uk/guidance/ipg658/chapter/2-The-condition-current-treatments-and-procedure>

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The National Institute for Health and Clinical Excellence (NICE) Medical Technologies Guidance (MTG) states that the use of Flow Diverting Embolisation devices in the NHS is supported by the current evidence when it is used in patients with complex 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 a Flow Diverting stent device offers the only possible means of treatment².

This latter subgroup consists of patients with rare, recently ruptured 'blood blister' aneurysms. Although there is no evidence that stents have advantages over other treatments in these cases, patients are at high risk of early haemorrhage, within a short time frame, associated with a high mortality rate.

Complex wide necked bifurcation aneurysms present a challenge for embolisation treatment. 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.

Alternatives to flow diverters include intra-saccular devices such as the Woven Mesh EndoBridge.

1.2 Aims and Objectives

This policy aims to define the commissioning position of NWJCC on the use of Intra-arterial Adjunct Devices for adults and young people (age 16 and over) for the treatment of intracranial aneurysms.

The objectives of this policy are to:

- ensure commissioning for the use of Intra-arterial Adjunct Devices is evidence based for the treatment of intracranial aneurysms,
- ensure equitable access to Intra-arterial Adjunct Devices for patients with intracranial aneurysms,
- define criteria for people with an intracranial aneurysm to access treatment,
- improve outcomes for people with intracranial aneurysm.

1.3 Current Service

Patients with any of the diagnoses specified in section 2.1 should be referred to the designated neurosurgical unit.

² <https://www.nice.org.uk/guidance/mtg10/chapter/1-Recommendations>

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- South, Powys, Mid and West Wales – Cardiff and Vale University Health Board
University Hospital of Wales
Heath Park
Cardiff
CF14 4X
- North Wales – The Walton Centre
Lower Lane
Liverpool
L9 7LJ

1.4 What NHS Wales has decided

NWJCC will fund the provision of Intra-arterial Adjunct Devices for residents of all seven Health Board in Wales within the criteria set out in section 2.1 of this policy.

1.5 Relationship with other documents

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

- **NHS Wales**
 - All Wales Policy: [Making Decisions in Individual Patient Funding requests \(IPFR\)](#).

NHS Wales Joint Commissioning Committee policies and service specifications

- [Adult Neurosurgery, Specialised Services Service Specification, CP178, March 2023, v1.0](#)
- **National Institute of Health and Care Excellence (NICE) guidance**
 - Neurointerventional Services for Acute Ischaemic & Haemorrhagic Stroke 2018
 - <https://www.england.nhs.uk/wp-content/uploads/2018/03/d04-interventional-neuroradiology-specification.pdf>
 - Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysms 2019
 - [https://www.nice.org.uk/guidance/ipg658/chapter/3-Committee considerations](https://www.nice.org.uk/guidance/ipg658/chapter/3-Committee%20considerations)
 - Overview Subarachnoid haemorrhage caused by a ruptured aneurysm: diagnosis and management 2022
 - <https://www.nice.org.uk/guidance/ng228/chapter/Recommendations#assessment-and-diagnosis>
 - Recommendations Subarachnoid haemorrhage caused by a ruptured aneurysm: diagnosis and management 2022

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- <https://www.nice.org.uk/guidance/NG228/chapter/Recommendations#managing-a-confirmed-aneurysmal-subarachnoid-haemorrhage>
- Overview Coil embolisation of ruptured intracranial aneurysms Guidance NICE 2005
- <https://www.nice.org.uk/guidance/ipg106>
- Pipeline Flex embolisation device with Shield Technology for the treatment of complex intracranial aneurysms
- <https://www.nice.org.uk/guidance/mtg10/chapter/1-Recommendations>

- **Relevant NHS England policies**
 - Clinical Commissioning Policy Statement: Flow Diverting Devices for Intracranial Aneurysms April 2013 Reference : NHSCB/D03/PS/a
<https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2013/10/d03-ps-a.pdf>

- **Other published documents**
 - [Summary pCONUS2 Bifurcation Aneurysm Implant for complex intracranial aneurysms Advice NICE 2020](https://www.nice.org.uk/advice/mib222/chapter/The-technology)
<https://www.nice.org.uk/advice/mib222/chapter/The-technology>
 - Transition and handover from children's to adult health service
<https://www.gov.wales/transition-and-handover-childrens-adult-health-services>

2. Criteria for Commissioning

The NHS Wales Joint Commissioning Committee will approve funding of Intra-arterial Adjunct Devices for the treatment of intracranial aneurysms in line with the criteria identified in this policy.

2.1 Inclusion Criteria

The criteria for treatment are shown below. These should be established through an assessment:

Elective Pathway

- Unruptured intradural saccular aneurysm;
- Unruptured intradural fusiform aneurysm;
- Unruptured intradural aneurysm;
- Any symptomatic extradural aneurysm (including cavernous carotid).

Acute Bleeds

- Acutely 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 stent 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.

Patients should also be aware of the need for regular and long term monitoring and follow up by the Neurovascular team.

2.2 Exclusion Criteria

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)

2.3 Continuation of Treatment

Healthcare professionals are expected to review a patient's health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given.

2.4 Acceptance Criteria

The service outlined in this policy is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.5 Transition Arrangements

Transition arrangements should be in line with [Transition from children's to adults' services for young people using health or social care services NICE guidance NG43 and the Welsh Government Transition and Handover Guidance](#).

Transition involves a process of preparation for young people and their families for their transition to adulthood and their transition to adult services.

The transition process should be a flexible and collaborative process involving the young person and their family as appropriate and the service.

The manner in which this process is managed will vary on an individual case basis with multidisciplinary input often required and patient and family choice taken into account together with individual health board and environmental circumstances factored in.

If surgery is likely to take place after the patient's 16th birthday, a discussion should take place with the adult service.

2.6 Patient Pathway (Annex i)

Patients with any of the diagnoses specified in section 2.1 should be referred to the designated neurosurgical unit.

Acute Pathway

The Neurosurgical centre providing a neurovascular service should allow rapid investigation and management of emergency cases. Patients with confirmed aneurysmal subarachnoid haemorrhage are referred to a neurosurgeon and discussed urgently with the interventional radiologist

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Patients are admitted to the service within 24 hours of presentation and are treated within 48 hours.

The management of each acute referral should be discussed and agreed by the neurovascular surgeon, interventional neuroradiologist and where appropriate the neuro-critical care specialist.

Elective Pathway

Patients are referred to the neurosciences centre for review, patients are discussed at the weekly MDT. A treatment plan will be discussed with the patient and they are placed on the waiting list.

2.7 Designated Centres

- South, Mid and West Wales – Cardiff and Vale University Health Board
University Hospital of Wales
Heath Park
Cardiff
CF14 4XW
- North Wales – The Walton Centre
Lower Lane
Liverpool
L9 7LJ

2.8 Exceptions

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

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

Further information on making IPFR requests can be found at: [Individual Patient Funding Requests](#)

2.9 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information as specified in annex ii and annex iii to the NWJCC Information Team via nwjccinformation@wales.nhs.uk

2.10 Responsibilities

Referrers should:

- inform the patient and/or their parent or guardian that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

Clinicians considering treatment should:

- discuss all alternative treatments with the patient and/or their parent or guardian;
- advise the patient and/or their parent or guardian of any side effects and risks of the potential treatment
- inform the patient and/or their parent or guardian that treatment is not routinely funded outside of the criteria in the policy, and

In all other circumstances an IPFR must be submitted.

3. Evidence

NWJCC is committed to regularly reviewing and updating all of its commissioning policies based upon the best available evidence of both clinical and cost effectiveness.

The evidence to support the recommendations with the policy are derived and have been directly adapted from the documents listed below. An updated evidence review has been commissioned by NWJCC to inform the next update of this commissioning policy.

3.1 References

The evidence to support the recommendations within the policy are derived from the documents listed in Section 1.6.

3.2 Date of Review

This document is scheduled for review before September 2027 where we will check if any new evidence is available. If no new evidence or intervention is available the review date will be progressed.

If an update is carried out the policy will remain extant until the revised policy is published.

4. 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 NHS Wales Joint Commissioning 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.

5. Putting Things Right:

5.1 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.

If 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 NWJCC.

5.2 Individual Patient Funding Request (IPFR)

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

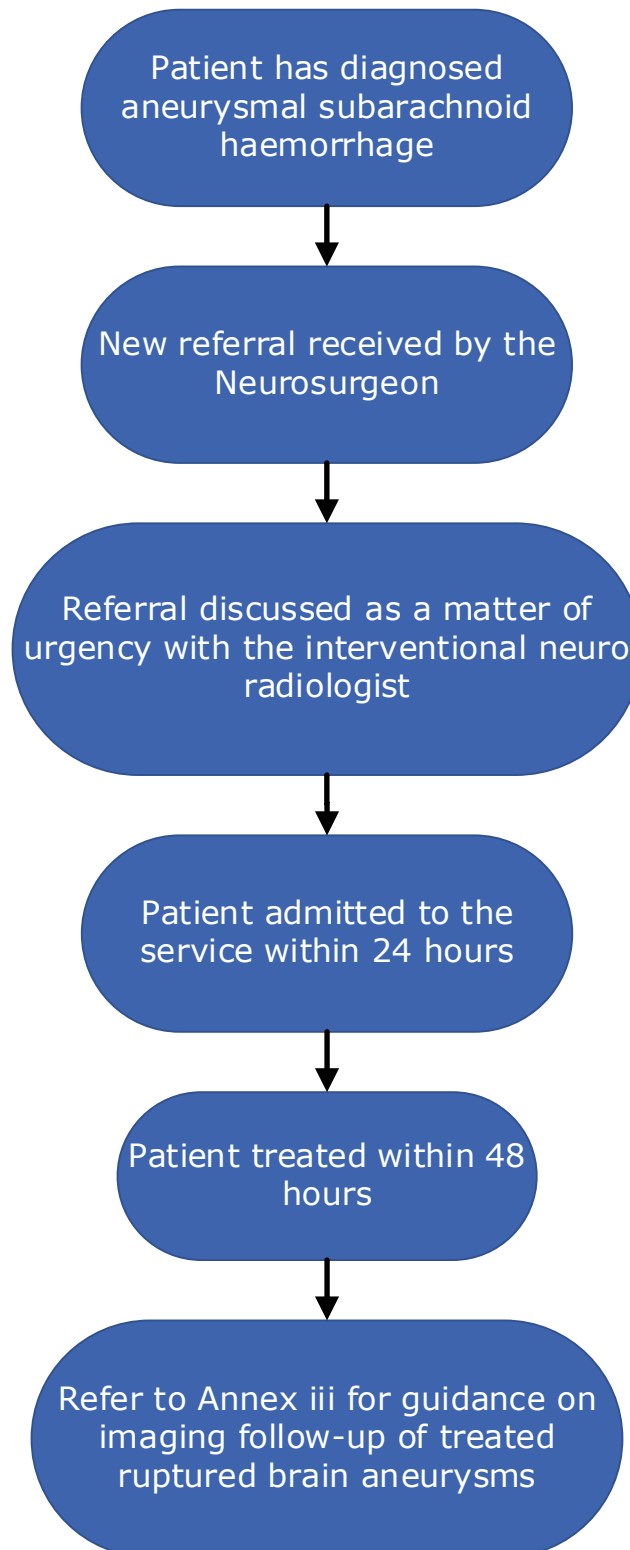
If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

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

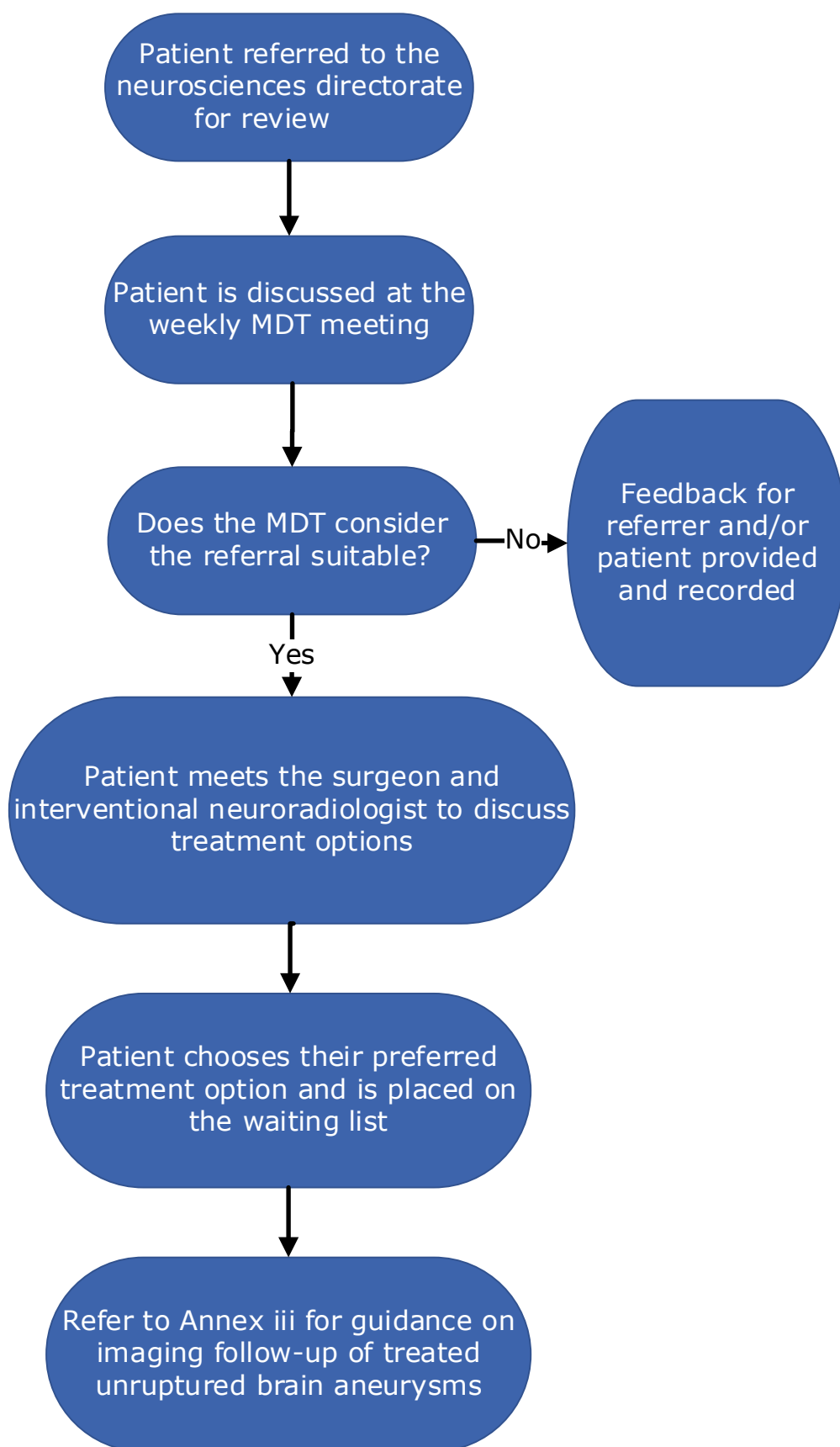
Further information on making IPFR requests can be found at: [Individual Patient Funding Requests](#)

Annex i Patient Pathway

Acute Pathway



Elective Pathway



Annex ii Codes

Code Category	Code	Description
ICD	I67.1	Cerebral aneurysm, nonruptured

Annex iii Clinical Outcomes and Quality Criteria

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 ipsilateral 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;
- Complete occlusion of a very large aneurysms within 2 years;
- 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. Where possible services are to implement systems for patients and families to provide feedback on their care experiences.

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, NWJCC.

Imaging follow-up of treated unruptured brain aneurysms

Imaging of follow-up guidelines for treated unruptured brain aneurysm remains similar to the treatment of ruptured aneurysms. In general, treatment is geared towards best occlusion rates, therefore necessitating use of adjunct devices such as intracranial stents.

- Coiling/ Balloon assisted coiling- MRA only at 6 months, 18 months and 5 years.
- Additional imaging such as IVDSA or cerebral angiography may also be required depending on the patient circumstances.

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- Complex aneurysms- as per report on PACS if follow up arrangements vary
- If the 5 year MRA follow-up shows no recurrence of the treated brain aneurysm, it is advised to stop imaging follow-up.
- The present evidence demonstrates very low risk of the repeat subarachnoid haemorrhage in these treated brain aneurysms.
- If there are untreated other brain aneurysms in the same patient, then each case is discussed individually in the neurovascular multidisciplinary meeting and a combined outcome is recorded and followed.

Basilar aneurysms are sometimes followed up for a longer time as these aneurysms natural history demonstrate higher growth recurrence rate

- Neurosurgical clipping of brain aneurysms: IV DSA or CT angiogram is advised to follow-up of clipped brain aneurysms. It is advisable to perform the first IV DSA/CTA within 48 hours of treatment if the patient is stable to have a baseline. Further follow-up is recommended at 6 months and 2 years. Long-term follow-up is debatable, neurovascular neurosurgeon to recommend in MDT.
- MRI compatible clips can have MRA preferentially at 6 months and 2 years.

Annex iv Abbreviations and Glossary

Abbreviations

BBA	Blood Blister Aneurysms
DSA	Digital Subtraction Angiography
EQIA	Equality Impact Assessment
IPFR	Individual Patient Funding Request
MRA	Magnetic Resonance Angiography
MTG	Medical Technologies Guidance
MDT	Multi-Disciplinary Team
NICE	National Institute for Health and Clinical Excellence
NWJCC	NHS Wales Joint Commissioning Committee

Glossary

Aneurysm

An aneurysm is a bulge in a blood vessel caused by a weakness in the blood vessel wall, usually where it branches. As blood passes through the weakened blood vessel, the blood pressure causes a small area to bulge outwards like a balloon.

Blood blister-like aneurysm

Blood blister aneurysms (BBAs) are rare aneurysms affecting non-branched points of intracerebral arteries. Due to their small size and fragility, BBAs are prone to rupture, and can be challenging to diagnose and treat.

Coils

Tiny coils are deployed directly into the aneurysm in a minimally invasive interventional procedure using a micro catheter to induce clotting with the aneurysm and prevent rupture. Coils come in various shapes, sizes and configurations and are deployed by the interventional neuroradiologist depending on the anatomy of the aneurysm.

The Flow Diverters Device (Stent)

The Flow Diverter device commonly known as a stent is a self-expanding blood flow diverter that is a common procedure to treat a brain aneurysm placed across the neck of an intracranial aneurysm. There are various types of diverters deployed for use depending on the anatomy of the brain aneurysm. Flow Diverters allow for treatment of previously untreatable aneurysms. They may be used as an alternative to coiling, most commonly

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stent- assisted coiling, particularly in patients for whom standard coiling and/or stenting is unsuitable or for whom previous coiling/clipping procedures have failed. Flow diverters are now routinely used to treat blood blister aneurysm.

Flow diverters are placed within the parent artery rather than inside the aneurysm and alter blood flow at the aneurysm neck and parent vessel site. This allows for a gradual thrombosis of the aneurysm occurring over time and shrinkage of the aneurysm whilst preserving small side branches in most cases.

Individual Patient Funding Request (IPFR)

An IPFR is a request to NHS Wales Joint Commissioning Committee (NWJCC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

NHS Wales Joint Commissioning Committee (NWJCC)

NWJCC is a joint committee of the seven local health boards in Wales. The purpose of NWJCC is to ensure that the population of Wales has fair and equitable access to the full range of Tertiary Services. NWJCC ensures that services within our portfolio are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.