



Australian Government

Department of Health

Application Form

(New and Amended

Requests for Public Funding)

(Version 2.4)

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires in order to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Phone: +61 2 6289 7550

Fax: +61 2 6289 5540

Email: hta@health.gov.au

Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant): [Medtronic Australasia Pty Ltd](#)

Corporation name: [Medtronic Australasia Pty Ltd](#)

ABN: [REDACTED](#)

Business trading name: [Medtronic Australasia Pty Ltd](#)

Primary contact name: [REDACTED](#)

Primary contact numbers

Business: [REDACTED](#)

Mobile: [REDACTED](#)

Email: [REDACTED](#)

Alternative contact name: [REDACTED](#)

Alternative contact numbers

Business: [REDACTED](#)

Mobile: [REDACTED](#)

Email: [REDACTED](#)

1. (a) Are you a consultant acting on behalf of an Applicant?

- Yes
 No

(b) If yes, what is the Applicant(s) name that you are acting on behalf of?

2. (a) Are you a lobbyist acting on behalf of an Applicant?

- Yes
 No

(b) If yes, are you listed on the Register of Lobbyists?

- Yes
 No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Endovascular insertion of flow diversion device (FDD) for the treatment of unruptured intracranial aneurysms (UIAs)

4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

An intracranial aneurysm, also known as a cerebral or brain aneurysm, is an abnormal, localised dilation that balloons or bulges from an artery that supplies blood to the brain. The aneurysm occurs when a weakness develops in the wall of an artery supplying blood to the brain.

UIAs are often asymptomatic and are identified incidentally through imaging for symptoms unrelated to the UIA. Large or giant aneurysms frequently present with symptoms of mass effect on the cranial nerves (Rooij & Sluzewski 2008), such as headache, nausea/vomiting, visual disturbances or loss of consciousness (Brisman et al., 2006).

The prevalence of UIAs in a population without comorbidities is estimated as 3.2%. The majority of UIAs remain stable, however, a small proportion will eventually rupture causing aneurysmal bleeding in the brain. The clinical consequences of a ruptured aneurysm are serious and associated with significant morbidity and mortality (Vlak et al., 2011).

5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

The proposed medical service is the endovascular insertion of a FDD within the parent vessel spanning the neck of the UIA. The FDD functions by reducing blood flow from the parent artery into the aneurysm - as a result blood in the aneurysm stagnates and undergoes thrombosis – i.e. embolizes – and the aneurysm resolves.

FDD was originally developed to treat intracranial aneurysms with complex morphologies. These are challenging to treat with endovascular coiling: outcomes have been poor with suboptimal aneurysm occlusion and recurrence requiring re-intervention in complex cases.

FDD is much less invasive than microsurgical clipping which requires a craniotomy. There is a high clinical need for a safe and effective procedure to be listed on the Medicare Benefits Schedule (MBS) that overcomes the shortcomings of current treatments. Importantly, FDD represents a treatment option in a small proportion of patients currently left untreated due to the complexity of the aneurysm.

6. (a) Is this a request for MBS funding?

- Yes
 No

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

- Amendment to existing MBS item(s)
 New MBS item(s)

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

35412

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

- i. An amendment to the way the service is clinically delivered under the existing item(s)

- ii. An amendment to the patient population under the existing item(s)
- iii. An amendment to the schedule fee of the existing item(s)
- iv. An amendment to the time and complexity of an existing item(s)
- v. Access to an existing item(s) by a different health practitioner group
- vi. Minor amendments to the item descriptor that does not affect how the service is delivered
- vii. An amendment to an existing specific single consultation item
- viii. An amendment to an existing global consultation item(s)
- ix. Other (please describe below):

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

Not applicable

- i. A new item which also seeks to allow access to the MBS for a specific health practitioner group
- ii. A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
- iii. A new item for a specific single consultation item
- iv. A new item for a global consultation item(s)

(f) Is the proposed service seeking public funding other than the MBS?

- Yes
- No

(g) If yes, please advise:

N/A

7. What is the type of service:

- Therapeutic medical service
- Investigative medical service
- Single consultation medical service
- Global consultation medical service
- Allied health service
- Co-dependent technology
- Hybrid health technology

8. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):

N/A

- i. To be used as a screening tool in asymptomatic populations
- ii. Assists in establishing a diagnosis in symptomatic patients
- iii. Provides information about prognosis
- iv. Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
- v. Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

- Pharmaceutical / Biological
- Prosthesis or device
- No

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

- Yes
- No

N/A

(b) If yes, please list the relevant PBS item code(s):

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

- Yes (please provide PBAC submission item number below)
- No

N/A

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

Trade name: N/A

Generic name: N/A

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

- Yes
- No

(b) If yes, please provide the following information (where relevant):

Billing code(s): N/A

Trade name of prostheses: N/A

Clinical name of prostheses: N/A

Other device components delivered as part of the service: N/A

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

Yes

No

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?

Yes

No

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

Culpan Medical Pty Ltd

Getz Healthcare Pty Ltd

Stryker Australia Pty Ltd

12. Please identify any single and / or multi-use consumables delivered as part of the service?

Single use consumables: sheath, support catheter, microcatheter and guidewire

Multi-use consumables: N/A

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

Type of therapeutic good: Implanted prosthesis (ie, Pipeline Embolization Device)

Manufacturer's name: Micro Therapeutics Inc

Sponsor's name: Medtronic Australasia Pty Ltd

- (b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

- Class III
 AIMD
 N/A

14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

- Yes (If yes, please provide supporting documentation as an attachment to this application form)
 No

- (b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

- Yes (if yes, please provide details below in table)
 No

Table 1 TGA registered flow diversion product

ARTG number	Product description	Intended purpose	Sponsor
251273	Pipeline Flex Embolization Device with Shield Technology – stent, vascular, intracranial	The PED with Shield Technology is intended for endovascular embolization of cerebral aneurysms.	Medtronic Australasia Pty Ltd
230661	Pipeline Flex Embolization Device - Stent, vascular, intracranial	The PED is intended for endovascular embolization of cerebral aneurysms.	Medtronic Australasia Pty Ltd
186413	Pipeline Embolization Device - Stent, vascular, intracranial	The PED is intended for endovascular embolization of cerebral aneurysms.	Medtronic Australasia Pty Ltd
220724	FRED Flow Re-Direction Endoluminal Device - Stent, vascular, intracranial	The FRED system is intended for endovascular embolization of intracranial neurovascular aneurysms, may be used with embolic coils for the treatment of intracranial neurovascular lesions.	Culpan Medical Pty Ltd

ARTG number	Product description	Intended purpose	Sponsor
155086	Intracranial self-expanding stent SILK - Stent, vascular, intracranial	SILK stents are intended for the treatment of intracranial aneurisms. The SILK stent is an Nitinol stent which is introduced into the intracranial vessels via a delivery wire and introducer and catheter for placement.	Getz Healthcare Pty Ltd
283662	Surpass Streamline Flow Diverter - Stent, vascular, intracranial	The Surpass Flow Diverter is indicated for use for the treatment of saccular or fusiform intracranial aneurysms arising from a parent vessel with a diameter of ?2.5 mm and ?5.3 mm ^a	Stryker Australia Pty Ltd

Source: Therapeutic Goods Administration, accessed 7 March 2018.

^aAs per ARTG website - it is not clear what the '?'s refer to.

Flow diverters/embolization devices are sometimes referred to as flow-diverting stents. This is somewhat inaccurate – although both devices are mesh-like metal tubes, the design and intended use is very different. Flow-diverters are less porous than stents, designed to redirect blood flow from intracranial aneurysms and to enable parent artery reconstruction. Intracranial stents are designed to support endovascular embolization of intracranial aneurysms. This is achieved by bridging the aneurysm neck to keep coils deposited inside the aneurysm in place. Medtronic Pipeline embolization devices (PEDs) are a braided, multi-alloy, mesh cylinder woven from platinum/tungsten and cobalt-chromium-nickel alloy wires, with 65-70% porosity. The Medtronic intracranial Solitaire AB stent is laser cut from Nitinol alloy. In addition, the metal surface area of PEDs is 30-35%, far exceeding the 6.5 to 9.5% coverage for regular intracranial stents.

15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

- Yes (please provide details below)
 No

N/A

Date of submission to TGA:

Estimated date by which TGA approval can be expected:

TGA Application ID:

TGA approved indication(s), if applicable:

TGA approved purpose(s), if applicable:

16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

- Yes (please provide details below)
 No

N/A

Estimated date of submission to TGA:

Proposed indication(s), if applicable:

Proposed purpose(s), if applicable:

PART 4 – SUMMARY OF EVIDENCE

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
1.	Retrospective cohort study; 1:3 matched pair comparison	Chalouhi 2013b. Comparison of flow diversion and coiling in large unruptured intracranial saccular aneurysms.	A significantly higher proportion of aneurysms treated with PED (86%) achieved complete obliteration compared with coiled aneurysms (41%; $P < 0.001$). Retreatment was necessary in fewer patients in the PED group (2.8%) than the coil group (37%; $P < 0.001$).	http://stroke.ahajournals.org/content/44/8/2150	2013
2.	Retrospective cohort study; 1:4 matched pair comparison	Chalouhi 2014. Extending the indications of flow diversion to small, unruptured, saccular aneurysms of the anterior circulation.	At follow-up, a higher proportion of aneurysms treated with PED (80%) achieved complete obliteration compared with stent-coiled aneurysms (70%) ($P = 0.2$). Rate of periprocedural complications were similar between groups.	https://www.ncbi.nlm.nih.gov/pubmed/24253543	2014
3.	Retrospective cohort study with historical control, matched comparison; consecutive; III-3	Chalouhi 2017. Matched Comparison of Flow Diversion and Coiling in Small, Noncomplex Intracranial Aneurysms.	Complete occlusion (100%) at follow-up was significantly higher in patients treated with PED (70%) than coiling (47.5%, $P = 0.04$). A significantly higher proportion of coiled patients (32.5%) required retreatment compared with FD (5%, $P = 0.003$). All patients achieved a favourable outcome (modified Rankin Scale: 0-2) regardless of group.	https://www.ncbi.nlm.nih.gov/pubmed/28402491	2017

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
4.	Retrospective, cohort study	Di Maria 2015. Flow Diversion versus Standard Endovascular Techniques for the Treatment of Unruptured Carotid-Ophthalmic Aneurysms.	No statistically significant difference was found between complication (P = .9) and morbidity rates (P = .6). Occlusion rates between the 2 groups differed significantly in favour of PED at 12 months (P < .001) and at the latest follow-up (P < .005).	https://www.ncbi.nlm.nih.gov/pubmed/26272972	2015
5.	Retrospective, cohort, consecutive, matched pair 1:2 by aneurysm diameter	Durst 2016. Endovascular treatment of ophthalmic artery aneurysms: ophthalmic artery patency following flow diversion versus coil embolization	Treatment of ophthalmic arteries b PED vs coiling. Complete occlusion at 12 months was more common with PED than coiling (74% vs 47%; p=0.089). Retreatments were more common following coiling than PED (24% vs 11%; p=0.304). Permanent morbidity rates were not significantly different between the PED and coiling cohorts (11% vs 3%; p=0.255).	https://www.ncbi.nlm.nih.gov/pubmed/26354944	2016
9	Retrospective, consecutive	Miller 2014. Impact of Endovascular Technique on Fluoroscopy Usage: Stent-Assisted Coiling versus Flow Diversion for Paraclinoid Internal Carotid Artery Aneurysms.	Complete occlusion was significantly higher in PED (80%) vs 60% in SAC cohort. There were no procedural related deaths in either group. No PED patients had permanent neurological deficit compared with 5% of SAC patients/	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4291792/	2014

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
11.	Retrospective 2 cohort study	Petr 2016. Current Trends and Results of Endovascular Treatment of Unruptured Intracranial Aneurysms at a Single Institution in the Flow-Diverter Era.	There were no significant differences in the immediate (P=0.43) and mid-/long-term complication rates (P=0.54) between FD and coiling groups. Periprocedural neurologic morbidity and mortality rates were 2.1% and 0.5% in the coiling group and 2.5% and 1.6% in the FD group. Patients with coiling were more likely to be retreated than those with FD (14.8% versus 5.7%, P=0.009).	https://www.ncbi.nlm.nih.gov/pubmed/26797138	2016
12.	Retrospective, 4 cohort study	Zanaty 2014. Flow Diversion Versus Conventional Treatment for Carotid Cavernous Aneurysms.	One hundred fifty-seven patients with 167 cavernous carotid aneurysms were treated using PED placement, coiling, SAC, and carotid vessel destruction. The rate of complete occlusion was 81.36% (48/59) for PED, 42.25% (39/71) for SAC, 27.27% (6/22) for coiling, and 73.33% (11/15) for carotid vessel destruction. Retreatment was needed in patients with aneurysm size >15 mm (OR, 2.67; P=0.037) and those who were not treated with PED (PED: OR, 0.16; P=0.006).	https://www.ncbi.nlm.nih.gov/pubmed/25052318	2014

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
13.	Prospective, interventional, single arm, multi-centre	PUFS. Long-term clinical and angiographic outcomes following pipeline embolization device treatment of complex internal carotid artery aneurysms: five year results of the pipeline for uncoilable or failed aneurysms trial. Becske 2017.	The study included 107 patients with unruptured large and giant wide-neck aneurysm, and PED placement was successful in 107/108 patients. Complete occlusion at 1, 3 and 5 years was achieved in 86.8%, 93.4% and 95.2% of aneurysms respectively. Six aneurysms (5.7%) required retreatment. The rate of new serious device related events at 1, 3 and 5 years was 1%, 3.5% and 0% respectively. Four patients died (3.7%), with no delayed neurological deaths or haemorrhagic/ischaemic cerebrovascular event observed beyond 6 months post procedure. No recanalizations in previously occluded aneurysms was observed. Of the patients with 5-year follow up, 96.3% had modified Rankin Scale scores ≤ 2 . The authors concluded that PED offers a safe and effective treatment of large or giant intracranial internal carotid artery aneurysms, including those who failed previous treatment.	https://www.ncbi.nlm.nih.gov/pubmed/28362885	2017
14.	Prospective, interventional, single-arm, multi-center	PREMIER trial. Prospective, Multi-Center Study of Flow Diversion for Small and Medium-Sized Aneurysms: Results of the Premier Trial	The study included 141 patients with wide-neck, small/medium UIA ≤ 12 mm. Technical success was achieved in 99.3%. At 1 year, complete occlusion was achieved in 83.5% of patients and 2.1% had experienced a major stroke or neurological death.	https://professional.heart.org/idc/groups/ahamah-public/@wcm/@sop/@scon/documents/downloadable/ucm_492111.pdf	2017

* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

SAC=stent-assisted coiling; PED=Pipeline embolization device; FD=flow diversion; UIA=unruptured intracranial aneurysm.

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.*

**** If the publication is a follow-up to an initial publication, please advise.*

17. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.

#	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
1.	RCT, open-label	LARGE Aneurysm Randomized Trial: Flow Diversion Versus Traditional Endovascular Coiling Therapy (LARGE)	FD versus coiling. Study was terminated due to rarity of disease	NCT01762137	N/A
2.	RCT, open-label	Study of Complex Intracranial Aneurysm Treatment (SCAT)	The study is active, but not recruiting. FD vs cerebral revascularization with trapping of aneurysm in complex intracranial aneurysms.;	NCT03269942	N/A
3.	RCT, single-blind (outcomes assessor)	DIVERT. Diversion of Flow in Intracranial VErtеbral and Blood Blister-like Ruptured Aneurysms Trial: A Randomized Trial Comparing Pipeline Flow Diversion and Best-Standard-Treatment (DIVERT)	Study withdrawn due to rare aneurysms. FD vs best standard treatment (conservative, coiling +/-stenting, clipping, parent vessel occlusion +/- bypass in ruptured aneurysm of intracranial artery.	NCT01976026	N/A
4.	RCT, Phase II, open-label, multicenter	Flow Diverter Stent for Endovascular Treatment of Unruptured Saccular Wide-necked Intracranial Aneurysms (EVIDENCE)	Status is unknown. FD (Pipeline) vs coiling +/- stenting in unruptured, wide neck, intra-dural aneurysms amenable to either traditional endovascular strategy or FD	NCT01811134	N/A

#	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
5.	RCT, open-label, multicenter, post-marketing	MARCO POLO. Efficacy Trial of Intracranial Aneurysm Treatment Using Two Different Endovascular Techniques	Status is unknown. FD (SILK) vs coiling in untreated, UIA, saccular carotid siphon (diameter of ≥ 7 to ≤ 15 mm)	NCT01084681	N/A
6.	RCT, open-label (and a registry component)	Flow Diversion in Intracranial Aneurysm Treatment (FIAT)	Recruiting. FD vs best standard treatment (conservative management, or coiling +/- stenting, PVO +/- surgical bypass, clipping +/- bypass)	NCT01349582 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3287264/	Estimated completion Jan 2020

* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

**Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.

***Date of when results will be made available (to the best of your knowledge).

FD=flow diversion; PVO=parent vessel occlusion; RCT=randomised controlled trial; UIA=unruptured intracranial aneurysm.

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

- 18. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

Australian & New Zealand Society of Neuroradiology (ANZSNR) representing interventional neuroradiology (INR) practitioners (letter to be forwarded when available)

- 19. List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

ANZSNR representing INR practitioners also perform the comparator service, coiling.

Royal Australasian College of Surgeons – neurosurgery, represents neurosurgeons that perform clipping.

- 20. List the relevant consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

The Australian Stroke Foundation has been approached and the letter of support will be forwarded when available.

- 21. List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

Medtronic (Pipeline);

Getz Healthcare Pty Ltd (SILK)

Culpan Medical Pty (FRED)

Stryker Australia Pty Ltd (SURPASS)

- 22. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

Name of expert: REDACTED

Telephone number(s): REDACTED

Email address: REDACTED

Justification of expertise: REDACTED

Name of expert 2: REDACTED

Telephone number(s): REDACTED

Email address: REDACTED

Justification of expertise: REDACTED

Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.

PART 6 – POPULATION (AND PRIOR TESTS), INDICATION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

23. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality:

Intracranial aneurysm, or cerebral or brain aneurysms, develops when a weakness in the wall of an artery supplying blood to the brain result in a bulging or ballooning of the vessel. The bulge or sac consequently fills with blood and forms an aneurysm. UIAs can be classified as asymptomatic incidental aneurysms, symptomatic aneurysms and unruptured additional aneurysms in subarachnoid haemorrhage (SAH) patients (in those with multiple aneurysms) (Steiner et al 2013).

There are several different types of UIAs, including but not limited to saccular, fusiform, dissecting and mycotic aneurysms. The majority of aneurysms (90%) are termed saccular (Keddy 2006). The saccular aneurysm (also called berry) is spherical in shape and has a distinct neck. In contrast, the fusiform aneurysm appears like a dilation of the vessel, bulging on all sides, and has no distinct neck (Figure 1; Withers et al 2013). Fusiform aneurysms are often caused by atherosclerosis.

Dissecting aneurysms are rare (Baek & Kim 2014) and appear to be ballooning out on one side of the artery wall. Dissecting aneurysms may be caused by traumatic injury and develop from a lengthwise tear in the inner layer of the artery wall which causes blood to leak in between the layers of the wall¹. Mycotic aneurysms are very rare and are caused by an infection weakening the wall of the arteries.

As the name suggests, blister aneurysm has a blister-like appearance, typically small with a broad neck. This type of aneurysm is very rare and most commonly form non-branching sites of the intracranial arteries. This type of lesion is difficult to diagnose and manage (Chinchure et al 2014).

Another type of aneurysm is described as dysplastic. The suffix “plasia” means growth or development hence, dysplasia means abnormal. A dysplastic aneurysm can arise as a result of fibromuscular dysplasia but there can be many other health conditions that cause abnormal growth that can also form a dysplastic aneurysm. Fibromuscular dysplasia is a condition that causes stenosis and aneurysms of the arteries in the body.

Aneurysms may be described by their shape and size. NICE considers complex UIAs, specifically large/giant, wide-necked and fusiform aneurysms (Withers et al 2013). A wide neck is generally defined as ≥ 4 mm

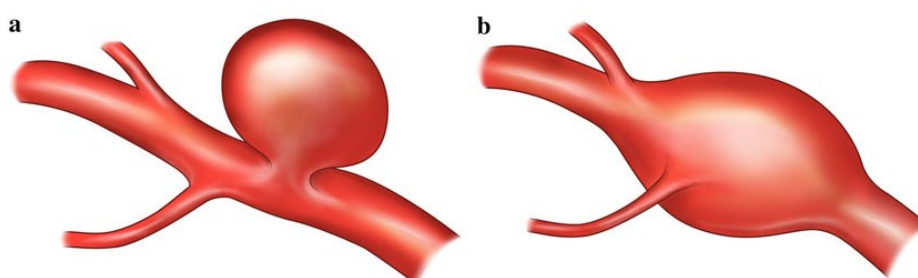


Figure 1 Representation of a) saccular aneurysm and b) fusiform aneurysm

Source: Withers et al (2013)

¹ <http://weillcornellbrainandspine.org/condition/aneurysm> (accessed 8th June 2018)

In many cases aneurysms are asymptomatic; and are only discovered incidentally, for example after magnetic resonance imaging (MRI) for unrelated symptoms such as headache or trauma (Vernooij et al., 2007). Other (usually larger) UIAs may be associated with neurological symptoms such as headache, nausea/vomiting, visual disturbances or loss of consciousness (Brisman et al., 2006). These symptoms arise from the compression of cranial nerves, and are termed symptoms of mass effect.

Whilst the majority of UIAs remain stable and clinically silent, a very small proportion will eventually rupture, causing aneurysmal subarachnoid haemorrhage (SAH). If and when a rupture occurs, the clinical consequences are serious; the mortality rate with conservative treatment is approximately 40%, and only a third of survivors experience a good neurologic outcome (Vlak et al., 2011).

Data suggests that the natural rupture history of UIAs is influenced by the size of the aneurysm. The International Study of Unruptured Intracranial Aneurysms (ISUIA) Investigators found 5-year rupture rates of 2.6 % for aneurysms of 7–12 mm, 14.5 % for those 13–24 mm and 40 % rupture rates for aneurysms of 25 mm or greater (Wiebers et al., 2003).

The prevalence of UIAs in a population without comorbidities is estimated as 3.2% (95% confidence interval [CI]: 1.6–5.2%). The prevalence is higher in those with comorbidities such as a positive family history of intracranial aneurysm of SAH or autosomal dominant polycystic kidney disease (Vlak et al., 2011).

24. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

As discussed in Q25, consistent with KOL feedback, there are four main population groups for which FD is proposed:

1. Patients with complex aneurysms (< 10 mm), suitable for endovascular or surgical therapy, with wide neck (> 4 mm), fusiform or dysplastic morphology.
2. Patients with aneurysms ≥ 10 mm, suitable for endovascular or surgical therapy.
3. Patients with aneurysms ≥ 10 mm, unsuitable for coiling, clipping or parent vessel occlusion (typically giant fusiform aneurysms arising at the skull base).
4. Patients with previously treated intracranial aneurysms of any size that have recanalized and require retreatment.

There is a clinical need for an effective and safe treatment option in the proposed populations that may overcome some of the short comings of current treatment options in the management of UIAs. The mechanism of action of FDD is reconstruction of the vessel and exclusion of the aneurysm from the circulation rather than occlusion of the aneurysm using coils. Introducing coils into the aneurysm carries a small risk of rupture at the time of procedure and may require additional stent placement to keep the coils in place, particularly in aneurysm of complex anatomy. FDD is less invasive to clipping which requires craniotomy. Aneurysms positioned at the skull base are often conservatively managed in current clinical practice as they are often unsuitable for coiling or clipping. FD is proposed to provide a treatment option for this population of patients that would otherwise remain untreated.

Previously treated intracranial aneurysms of any size that have recanalized and require retreatment are also ideal candidates for FDD and have a high clinical need of an effective treatment. These patients are particularly hard to treat without FD as the recanalization often forms a sharp corner, called a dog ear, which is very hard to get a coil to fit into.

Diagnosis and identifying patients suitable for treatment

UIAs can be classified as asymptomatic incidental aneurysms, symptomatic aneurysms and unruptured additional aneurysms in subarachnoid haemorrhage (SAH) patients (in those with multiple aneurysms) (Steiner et al 2013).

In many cases aneurysms are asymptomatic; and are only discovered incidentally, for example after magnetic resonance imaging (MRI) for unrelated symptoms such as headache or trauma (Vernooij et al., 2007). Other (usually larger) UIAs may be associated with neurological symptoms such as headache, nausea/vomiting, visual disturbances or loss of consciousness (Brisman et al., 2006). The symptoms arise

from the compression of cranial nerves. Therefore, the diagnosis of UIAs may be incidental, triggered by symptoms or through means of screening in high risk patients.

There are three main methods of imaging of aneurysms including magnetic resonance angiography (MRA), computed tomographic angiography (CTA) and digital subtraction angiography(DSA), each with varying advantages and disadvantages. The DSA is the most reliable test and considered the gold standard, however more invasive than the CTAs and MRAs (Thompson et al 2015). The patient is placed on an x-ray table and a small catheter is inserted in the femoral artery and guided through the vessel to the brain. Upon injection of contrast, images are taken that then are reviewed for abnormality. The MRA and CTA tests are non-invasive. In the CTA, the patient is placed on a table that slides into a CT scanner. Contrast material is injected into a vein and images of the blood vessels are reviewed for abnormalities. In the MRA, the patient is placed on a table that slides into the magnetic resonance scanner, and images of the blood vessels are reviewed to detect UIA².

The American Heart Association/American Stroke Association (AHA/ASA) guideline for the management of patients with UIAs (Thompson et al 2015) recommend screening in some patients with certain risk factors, as follows:

- 1 Patients with ≥ 2 family members with IA or SAH should be offered aneurysmal screening by CTA or MRA. Risk factors that predict a particularly high risk of aneurysm occurrence in such families include history of hypertension, smoking, and female sex (Class I; Level of Evidence B).
- 2 Patients with a history of autosomal dominant polycystic kidney disease, particularly those with a family history of IA, should be offered screening by CTA or MRA (Class I; Level of Evidence B), and it is reasonable to offer CTA or MRA to patients with coarctation of the aorta and patients with microcephalic osteodysplastic primordial dwarfism

The AHA/ASA 2015 guidelines recommend DSA over CTA and MRA for detection of UIA if surgical or endovascular treatment is considered, whilst acknowledging that CTA and MRA are also useful for identification (Thompson et al 2015).

In determining the approach to treatment, conservative, endovascular or surgical, the ASH guidelines recommend accurate measurement of the following be collected:

- Neck size
- Neck-to-dome ratio
- Measures of the aneurysm in 3 dimensions
- Relationship of aneurysm to surrounding vessels.

Determining patient eligibility for FD does not differ in comparison to diagnosis and identification approaches to determine patients eligible for comparator interventions. Similarly, the referral within the Australian clinical practice system does not differ between patients considered for FDD or coiling. Patients with UIAs considered for FDD or coiling are managed by INRs.

25. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

There are no current guidelines specific to Australia for the clinical management of patients with intracranial aneurysms. Relevant international guidelines include the American Heart

² http://www.strokeassociation.org/STROKEORG/AboutStroke/TypesofStroke/HemorrhagicBleeds/What-You-Should-Know-About-Cerebral-Aneurysms_UCM_310103_Article.jsp#.Ww4G3CC-m28 (accessed 8th June 2018)

Association/American Stroke Association (AHA/ASA) guideline (Thompson et al 2015) and the European Stroke Organisation (ESO) guidelines (Steiner et al 2013).

Table 2 outlines the recommendations for the management of patients with UIAs from the AHA/ASA and the ESO guidelines. In general, the guidelines suggest that both clipping and coiling treatments are effective, and that endovascular coiling is associated with a reduction in short term morbidity and mortality. However, because the relative durability of treatment effect for the procedures remains unknown, and the guidelines do not recommend one intervention over the other. Instead, most clinical advice emphasises a case-by-case approach to treating patients. The risks of aneurysm rupture must be weighed against the risks associated with the procedure itself. As summarised in Table 3, whilst clipping is associated with a lower risk of rupture, the invasive nature of the procedure exposes patients to a higher risk of complications and mortality compared with coiling.

Table 2 Recommendations of the AHA/ASA and ESO for the management of UIAs

Intervention	AHA/ASA	ESO
Comparative efficacy of surgical clipping versus endovascular coiling	Surgical clipping is an effective treatment for UIAs that are considered for treatment (Class I; Level of Evidence B). Endovascular coiling is an effective treatment for select UIAs that are considered for treatment (Class IIa; Level of Evidence B). Endovascular coiling is associated with a reduction in procedural morbidity and mortality over surgical clipping in selected cases but has an overall higher risk of recurrence (Class IIb; Level of Evidence B).	Although endovascular procedures might be associated with less immediate risk, the long-term risk and durability of treatment are not known and data from prolonged follow-up of treated patients are needed.
Flow diversion	Endoluminal FD represents a new treatment strategy that may be considered in carefully selected cases (Class IIb; Level of Evidence B). The long-term effects of these newer approaches remain largely unknown. Endovascular treatment of UIAs is recommended to be performed at high-volume centres (Class I; Level of Evidence B).	–
Conservative management	For patients with UIAs that are managed noninvasively without either surgical or endovascular intervention, radiographic follow-up with MRA or CTA at regular intervals is indicated. The optimal interval and duration of recommended follow-up are uncertain (Class I; Level of Evidence B). For patients with UIAs managed noninvasively without either surgical or endovascular intervention, a first follow-up study at 6 to 12 months after initial discovery, followed by subsequent yearly or every other year follow-up, may be reasonable (Class IIb; Level of Evidence C). For patients with UIAs that are managed noninvasively and in whom there are no	The larger the aneurysm the higher the chance of rupture (class II, level B) Considering risk (procedural risk, range 5–50%, vs. spontaneous rupture risk, 0–10%, per year) and benefit (life expectancy with or without minor deficit), the decision for or against intervention is a decision of the individual case taking into account patient-dependent factors (age, cigarette smoking and perhaps rupture from other aneurysm), aneurysmal factors (size, location), and the assumed risk of the intervention; therefore, the decision should be based on a multidisciplinary discussion of the individual case (class III, level C)

	contraindications to MRI, it may be reasonable to consider TOF MRA rather than CTA for repeated long-term follow-up (Class IIb; Level of Evidence C).	
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Abbreviations: TOF=time-of-flight; MRI=magnetic resonance imaging; CTA=computed tomographic angiography
Source: Thompson et al., 2015; Steiner et al., 2013

Table 3 Comparison of coiling and clipping with respect to morbidity, mortality and rebleeding rates

Event	Coiling (%)	Clipping (%)
Death	1.0–1.1	2.6–3.8
Morbidity	3.7–4.0	10.9–12.1
Re-bleeding	2.6	0-0.9

Source: Adapted from Keddy (2006)

The AHA/ASA suggests that FD may be considered in carefully selected cases and that this procedure may be performed at high-volume centres. However, these guidelines may not necessarily reflect current practice in Australia. In addition, the clinical evidence base for flow diversion has evolved considerably since these guidelines were produced. The Pipeline for Uncoilable or Failed Aneurysms (PUFS) trial provides 5-year data that supports the long-term effectiveness and safety of FDD in UIAs (Becske et al 2017). Therefore, to inform the management of ICAs in Australia, key opinion leaders (KOLs) that treat these patients were consulted (interventional neuroradiologist [INR]). The resulting clinical pathway is provided in Figure 5 (Appendix 1). The pathway focuses on UIAs, because very few ruptured ICAs would currently be considered for FDD in Australia. This in part is explained by the requirement of dual antiplatelet therapy 6-12 months post FDD procedure, which is best avoided in patients with bleeding.

The majority of aneurysms < 10 mm are considered suitable for surgical or endovascular treatment. Aneurysm morphology determines the most appropriate treatment option in these patients. Patients with complex anatomy, those aneurysms that have wide necks (> 4 mm), are fusiform or dysplastic are mostly managed using coiling with or without stent placement. Few patients with aneurysm < 10 mm, with complex anatomy are treated using microsurgical clipping. Both coiling and clipping are not ideal treatments in these types of aneurysms because the shape of the aneurysm means there is no distinct neck around which to fix the clip or that will keep the coils contained within the aneurysm. Coiling these aneurysms may require stent placement and/or require use of balloon remodelling. In contrast, FDD allows for vessel reconstruction with the aneurysms being excluded from the circulation and is suitable for aneurysms with complex anatomy. Consistent with KOL advice, FDD represents a treatment alternative in patients with aneurysms < 10 mm with complex anatomy.

Saccular aneurysms with narrow neck are mostly managed with coiling. The narrow neck means the coils can be contained in the aneurysm without requiring additional stents. KOL input suggests there is not a great clinical need of FDD as an alternative for the treatment of aneurysms with narrow neck, because these types of aneurysms are amenable to coiling as discussed above. Whilst FDD requires administration of dual antiplatelets 6-12 months post-procedure coiling does not (unless stent-assisted) which makes coiling the preferred treatment option in aneurysms with narrow neck suitable for endovascular treatment.

A small proportion of patients with aneurysms < 10 mm have incidental aneurysms that are <7 mm in size, and/or have no apparent risk factors for rupture. These patients are managed conservatively with periodic monitoring and would only require treatment if the size or shape of the aneurysm alters.

The majority of aneurysms ≥ 10 mm are also suitable for endovascular therapy or surgery. According to KOL feedback, the majority of these aneurysms are currently treated with coiling with or without stent placement, with some aneurysms treated with microsurgical clipping. Being a disruptive treatment that redirects blood flow away from the aneurysm, promoting growth of new endothelial lining across the aneurysm opening, FD represents a favourable treatment alternative in these patients. Compared with coiling, FDD is associated with higher occlusion rates and lower retreatment rates in this population (Chalouhi et al 2013b).

A small proportion of aneurysm ≥ 10 mm are not suitable for surgery or coiling. The aneurysms that tend not to be suitable for either surgery or coiling are the giant fusiform aneurysms arising at the skull base. These can be chronic dissecting aneurysms of the carotid or giant cavernous carotid aneurysms. When large enough, these aneurysms cause pressure on the nerves in the cavernous sinus, cranial nerves 3,4 and 6, causing paralysis of the eye muscles which results in double vision. These aneurysms are usually managed conservatively as all currently reimbursed treatment options are associated with risks. Coiling these aneurysms may increase the pressure on the nerves in turn worsening the symptoms. Microsurgical clipping of these aneurysms is invasive and requires major bypass. Carotid sacrifice of the vessel is associated with a 15-25% major stroke risk (KOL feedback). FDD provides a treatment option for these aneurysms that would otherwise be left untreated. Insertion of a FDD allows for reconstruction of the vessel, and by excluding the blood flow to the aneurysm results in shrinking of the aneurysm, thereby reducing the pressure and alleviating the symptoms at a lower procedural risk than clipping or vessel sacrifice.

As discussed in Q.24, according to KOL feedback, patients with previously treated intracranial aneurysms of any size that have recanalized and require retreatment are also ideal candidates for FDD. These aneurysms are particularly difficult to treat with coiling because as a result of the recanalization, a sharp corner is often formed, also called a 'dog ear', which is very hard to get a coil to fit into. As such, a high clinical need for an effective and safe re-treatment option therefore exists.

Therefore, consistent with KOL feedback, there are three main population groups for which a clinical need for FDD exists:

1. Patients with complex aneurysms (< 10 mm), suitable for endovascular or surgical therapy, with wide neck (> 4 mm), fusiform or dysplastic morphology.
2. Patients with large aneurysms (≥ 10 mm), suitable for endovascular or surgical therapy.
3. Patients with large aneurysms (≥ 10 mm), unsuitable for coiling, clipping or parent vessel occlusion typically giant fusiform aneurysms arising at the skull base.
4. Patients with previously treated intracranial aneurysms of any size that have recanalized and require retreatment.

PART 6b – INFORMATION ABOUT THE INTERVENTION

26. Describe the key components and clinical steps involved in delivering the proposed medical service:

The proposed medical service is the endovascular insertion of a wire-mesh FDD within the parent vessel spanning across the neck of the UIA. The FDD allows for flow through the parent vessel to be preserved whilst reducing blood flow into the aneurysm (Figure 2).

The reduction of blood flow from the parent artery into the aneurysm results in the blood within the aneurysm becoming stagnant and consequently undergoes thrombosis. This process promotes the generation of a new endothelium that eventually covers the aneurysm ostium, permanently excluding the aneurysm from the circulation. Excluding the aneurysm from the circulation removes the risk of rupture and thus prevents potentially fatal outcomes. The reduction in blood flow in the aneurysm commences almost immediately with 73.5% of aneurysms occluded at 12 months and 95.2% by 5 years (Beckske 2017).

The procedure is generally performed under general anaesthesia but depending on the complexity of the procedure and the medical condition of the patient may be performed using sedation. The patient is placed back down on an x-ray table. Heparin is injected throughout the procedure to prevent blood clots from forming.

Using standard interventional radiographic technique, the micro catheter is passed through the femoral artery and advanced so that the tip is placed ≥ 20 mm past the distal edge of the aneurysm. Prior to inserting of the FDD such as Pipeline, the micro catheter is gently retracted to reduce the slack in the micro catheter. The FDD device size is selected to match the labelled diameter to the target vessel diameter.

Once the FDD has been placed, the catheter is removed. Pressure is applied to the groin area for about 10 to 15 minutes so that the artery won't bleed. A bandage is tightly applied to the incision.

After the procedure the patient is observed and monitored as the anaesthesia or sedation wears off, with pain medication administered as appropriate. The patient is usually discharged the following day.

The patients will generally have a follow-up appointment approximately 1 months after the procedure, with a follow-up angiogram 3–6 months after the procedure to assess occlusion of the aneurysm.

Patients are generally pre-treated with dual antiplatelets with aspirin and clopidogrel with treatment continued for at least 6 months post procedure. The post-procedure antiplatelet protocol in an Australian study stipulated administration for 6 months in anterior location and 12 months post procedure in posterior location (McAuliffe et al 2012).

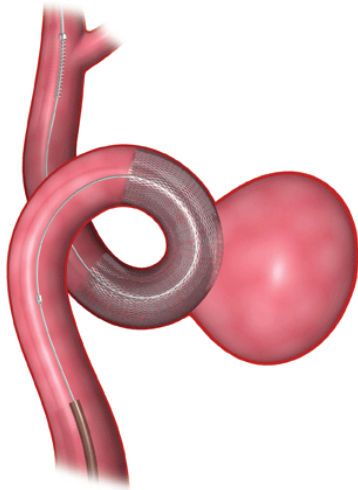


Figure 2 Pipeline Flow Diversion Device in UIA

27. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

The proposed medical service does not include a registered trademark component.

28. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

Patients with UIAs are currently managed using endovascular coiling and to a lesser extent by surgical clipping. The objective of the coiling procedure is to occlude the aneurysm by inserting multiple coils into the aneurysm. The insertion of coils is associated with a given small risk of rupture. Surgical clipping involves placing a small metallic clip or clips along the neck of the aneurysm, preventing blood from entering into the aneurysm sac. The clip remains in place after the procedure, and over time the aneurysm will shrink and heal. Clipping is a highly invasive procedure that involves accessing the aneurysm via craniotomy.

The proposed medical service involves the endovascular placement of a FDD into the parent artery of patients with UIAs. The FDD is a prosthesis that remains in the artery, and that allows the blood to flow through the artery whilst excluding circulation to the aneurysm which eventually shrinks away. In contrast to coiling, FD removes the need to enter the aneurysm, rather the objective is to reconstruct the parent vessel.

As such, the endovascular insertion of a FDD provides a new treatment approach to managing patients with UIA. As discussed in Q.39 there are some UIAs that are not suitable for coiling or clipping but for which FDD is suitable, for example large aneurysms at the skull of the neck. In this group of patients, listing FDD on the MBS would provide a treatment option.

29. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

The endovascular insertion of a FDD is performed by INRs, and as such, accessibility to the service may be limited by the availability of specialists in the local area where the patients resides. There are no other apparent limitations on the provision of the service.

The insertion of FDD is intended as a one off procedure, with a proportion of patients requiring re-treatment 2.8–10.3% (Chaloui et al 2013b; Chaloui et al 2014; Chaloui et al 2017).

30. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service:

The endovascular insertion of a FDD would be performed in hospital by a specialist (INR or neurosurgeon). Pre-operative DSA, intra-operative imaging and general anaesthesia would be administered at the same time as the proposed medical service. These resources are the same as those required for endovascular coiling +/- stents. The patient will in most cases be admitted overnight.

Dual antiplatelets such as aspirin and clopidogrel, are required in conjunction with the endovascular insertion of FDDs.

31. If applicable, advise which health professionals will primarily deliver the proposed service:

The procedure will predominantly be performed by interventional neuroradiologists (INR).

32. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

Not applicable

33. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

Not applicable

34. If applicable, advise what type of training or qualifications would be required to perform the proposed service as well as any accreditation requirements to support service delivery:

The Conjoint Committee for Recognition of Training in Interventional Neuroradiology (CCINR) was formed in 2014 to develop and monitor guidelines for certification of training in interventional neuroradiology (INR) in Australia and New Zealand (<http://www.ccinr.org.au/>). The CCINR would be an appropriate body to consult regarding training, qualification and accreditation requirements.

35. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select all relevant settings):

- Inpatient private hospital
- Inpatient public hospital
- Outpatient clinic
- Emergency Department
- Consulting rooms
- Day surgery centre
- Residential aged care facility
- Patient's home
- Laboratory
- Other – please specify below

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

The procedure will be performed in hospital (public or private), with the patient monitored and usually remaining in hospital overnight.

36. Is the proposed medical service intended to be entirely rendered in Australia?

- Yes
- No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

37. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service):

The proposed comparators for endovascular insertion of a FDD, consistent with current clinical management of patients (Q40) and current utilisation in clinical practice (Q46) are as follows:

1. Patients with aneurysms < 10 mm, suitable for endovascular or surgical therapy, with wide neck (> 4 mm), fusiform or dysplastic morphology. Comparator: coiling ± stenting
2. Patients with aneurysms ≥ 10 mm, suitable for endovascular or surgical therapy. Comparator: coiling ± stenting
3. Patients with aneurysms ≥ 10 mm, unsuitable for coiling, clipping or parent vessel occlusion typically giant fusiform aneurysms arising at the skull base. Comparator: conservative management
4. Patients with previously treated intracranial aneurysms of any size that have recanalized and require retreatment. Comparator: coiling ± stenting.

Patients with a previously treated aneurysm of any size that require re-treatment also constitute a population with high clinical need of an effective treatment. The current management of these patients is endovascular coiling.

There are two main treatments reimbursed on the MBS for the treatment of intracranial aneurysms, clipping (MBS 39800 and 39806) and endovascular coiling (MBS 35412). Ligation or grafting of the parent vessel is rarely used and not considered further. The MBS item descriptors for clipping, coiling, ligation and grafting are provided in Table 4. Details of each of these procedures are provided below.

Table 4 Relevant MBS items for potential comparators

MBS item	MBS item descriptor	Fee
Coiling		
35412	Intracranial aneurysm, ruptured or unruptured, endovascular occlusion with detachable coils, and assisted coiling if performed, with parent artery preservation, not for use with liquid embolics only, including aftercare, including intra-operative imaging, but in association with the following pre-operative diagnostic imaging items: - either 60009 or 60010; and - either 60072, 60073, 60075, 60076, 60078 or 60079	\$2,857.55
Clipping		
39800	ANEURYSM, clipping or reinforcement of sac	\$2,857.55
39806	ANEURYSM, or arteriovenous malformation, intracranial proximal artery clipping of	\$1,285.75
Ligation or grafting		
33100	ANEURYSM OF COMMON OR INTERNAL CAROTID ARTERY, OR BOTH, replacement by graft of vein or synthetic material	\$1,436.30
39812	INTRACRANIAL ANEURYSM or arteriovenous fistula, ligation of cervical vessel or vessels	\$631.75

The insertion of a FDD and coiling are both performed endovascularly via the femoral artery and are less invasive than surgical clipping which is performed via a craniotomy. As demonstrated in **Figure 3**, the utilisation of clipping has remained fairly stable with a slight decrease in utilisation in the last year. In stark contrast, the utilisation of endovascular coiling has increased steadily since its listing on the MBS. It is acknowledged that the MBS item codes for coiling and clipping do not differentiate between the treatment of ruptured versus unruptured intracranial aneurysms. Nevertheless, the MBS utilisation data suggests that should FDD be listed for the treatment of the proposed patient populations in those suitable for endovascular or surgical treatment, coiling would be the treatment that would most likely be replaced. Given the level of invasiveness is similar between FDD and coiling coupled with current utilisation of endovascular and surgical procedures on the MBS, coiling is the most appropriate comparator to FDD in the current application for aneurysms amenable to treatment (populations 1 and 2).

In the population of patients with aneurysms ≥ 10 mm that are not suitable for endovascular coiling (population 3), surgical clipping or parent vessel occlusion, conservative management is the proposed comparator. Suitability is discussed in more detail in Q40, however in short, these patients tend to have posteriorly located aneurysms with mass effect and for which the risk to benefit ratio of existing treatments is unfavourable.

Brief details of the respective treatment options follow below.

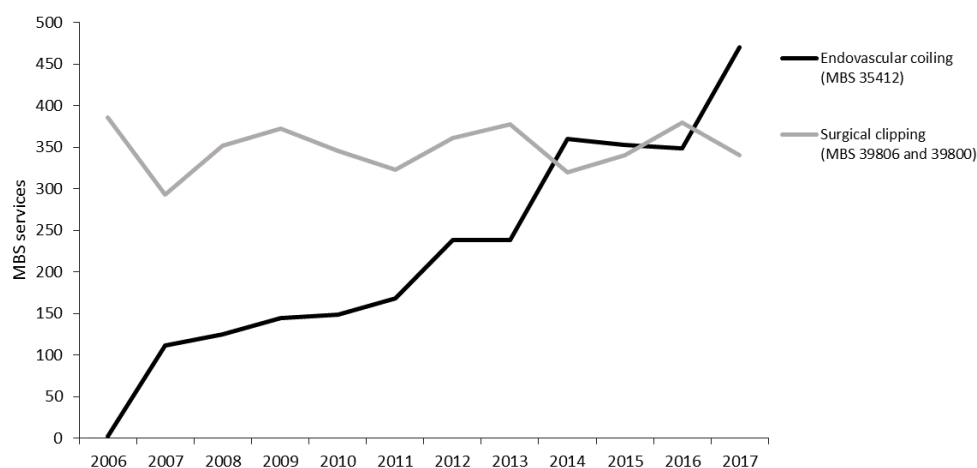


Figure 3 MBS utilisation of endovascular coiling and surgical clipping

Surgical clipping

Surgical clipping involves placing a small metallic clip or clips along the neck of the aneurysm, preventing blood from entering into the aneurysm sac. The clip remains in place after the procedure, and over time the aneurysm will shrink and heal. Clipping is a highly invasive procedure that involves accessing the aneurysm via craniotomy.

Coil embolization

Coil embolization of UIAs typically involve threading a catheter from an artery in the leg up to the aneurysm and placing a metal coil into the aneurysm guided by x-ray. The micro catheter is positioned within the aneurysm sac and a series of detachable coils are deployed into the aneurysm until progressive aneurysm occlusion occurs. Systemic heparinization is required for the duration of the procedure. This procedure allows for intra-aneurysmal thrombosis whilst maintaining parent vessel flow. Compared with surgical clipping, the coil embolization procedure is much less invasive given craniotomy is not required. The objective of the procedure is to occlude the aneurysm using coils, and entering the aneurysm is the

most dangerous part of the procedure given small risk of rupture. In contrast, FDD removes this need to enter the aneurysms, and rather the objective is to reconstruct the vessel whilst excluding the aneurysm.

The adjunct therapy of balloon remodelling and stent assistance allows coiling to be performed on aneurysms with wide neck. Balloon remodelling involves the temporary inflation of a balloon within the parent vessel during coil deployment in the adjacent aneurysm. This allows the coil mass to achieve stability at which point the balloon is deflated and removed. Stent assistance involves the placement of a thin wire-mesh stent within the parent vessel to serve as a scaffold for the coils that are placed into the aneurysm. Stent placement requires dual antiplatelet treatment (typically aspirin and clopidogrel), prior to and post-procedure. Ballooning typically does not require dual antiplatelet therapy post-procedure.

Conservative management

Conservative management involves periodic imaging every 12 months using MRI or less frequently CT scanning, to monitor the aneurysm. Patients with aneurysms less than 7 mm, without family history or risk factors may be managed conservatively. Another group of patients with large aneurysms who are not suitable for endovascular therapy or surgery may be left untreated due to no other treatment option.

38. Does the medical service that has been nominated as the comparator have an existing MBS item number(s)?

- Yes (please provide all relevant MBS item numbers below)
 No

Category 3 – THERAPEUTIC PROCEDURES
<p>MBS item: 35412</p> <p>Intracranial aneurysm, ruptured or unruptured, endovascular occlusion with detachable coils, and assisted coiling if performed, with parent artery preservation, not for use with liquid embolics only, including aftercare, including intra-operative imaging, but in association with the following pre-operative diagnostic imaging items:</p> <ul style="list-style-type: none">- either 60009 or 60010; and- either 60072, 60073, 60075, 60076, 60078 or 60079 <p>Fee: \$2,857.55 Benefit: 75% = \$2,143.20 85% = \$2,775.85</p>

39. Define and summarise the current clinical management pathways that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards including health care resources):

After the endovascular insertion of a FDD or coiling, it is anticipated patients would have an initial follow-up one month post-procedure with an angiogram 3-6 months post-procedure. At follow-up, imaging is performed to identify residuals, device migration, new aneurysms and any parent vessel changes (Thompson et al., 2015). A proportion of patients would require retreatment. According to KOL feedback FD is more likely to be used in patients who have recurrence after coiling.

40. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

- Yes
 No

(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted:

FDD will be used instead of the nominated comparator, coiling. Clinical evidence suggests that endovascular insertion of FDD has a lower rate of retreatment when compared to endovascular coiling (Chaloui et al 2013b). As such, it could reasonably be assumed that the utilisation of endovascular insertion of FDD will reduce the substituted endovascular coiling procedures at a rate greater than 1.

41. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline):

At the time of the procedure, the healthcare resource utilisations, including to pre- and intra-operative imaging, anaesthesia, professional attendance time and hospitalisation stay, associated with FDD is expected to be similar to those associated with coiling. However, a proportion of aneurysms treated with endovascular coiling require additional stent placement – this is not required for FDD. Both FDD and coiling may require balloon remodelling in a small proportion of patients. The follow up of patients after the procedure is the same for FDD and coiling.

The proportion of patients requiring retreatment is significantly lower with FDD compared with coiling, especially in larger aneurysms (2.8% vs 36.7% in aneurysms > 10 mm; Chaloui et al 2013b), representing healthcare resource utilisation savings for FDD.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

42. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

The clinical claim for FDD relative to endovascular coiling in UIAs is superior effectiveness (based on complete occlusion and significantly lower retreatment rates) and non-inferior safety (based on procedural complications and long term rates of stroke and mortality).

The clinical claim for FDD relative to conservative management is superior effectiveness based on mortality and rupture rates from natural history data.

43. Please advise if the overall clinical claim is for:

- Superiority
 Non-inferiority

44. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Safety Outcomes:

Procedural complications (stroke, intracranial haemorrhage, perforation, device migration, mortality)

Long term complications (stroke, mortality, restenosis, rupture)

Clinical Effectiveness Outcomes:

Complete occlusion

Retreatment or recurrence

Modified Rankin scale (patient function/disability measure/quality of life measure)

Neurological symptoms (alleviation of mass effect)

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

45. Estimate the prevalence and/or incidence of the proposed population:

UIAs are often asymptomatic and therefore remain undiagnosed. Furthermore, as outlined in Q25 aneurysms of size less than 7 mm, in patients without family history or other risk factors, are regularly managed conservatively, and remain untreated. As such, incidence of diagnosis and treatment of UIAs, as opposed to the underlying prevalence of the condition, is proposed to be the most accurate method for estimating the proposed population. The disparity between the two measures is illustrated below through a comparison of UIA prevalence estimates and the reported number of UIA treatment procedures performed in Australian hospitals.

A meta-analysis of 83 study populations, across 21 countries, including 94,912 patients reported a UIA prevalence of 3.2% (Vlak 2011). Vlaks' (2011) prevalence estimates are based on population screening studies and post-mortem studies, therefore capturing the underlying presence of the disease irrespective of diagnosis and treatment requirements. Applying this prevalence to the Australian population in 2019 (25,862,832) results in an estimated patient population of 830,000 with UIAs.

In comparison, AIHW procedure statistics data for Australian hospitals reports between 2,024 and 2,351 procedures for endovascular occlusion (assumed to comprise coiling and FDD) or surgical clipping of cerebral aneurysms between 2011-12 and 2015-16, Table 5. It is acknowledged that these procedures include both ruptured and unruptured aneurysms. However, AIHW principal diagnosis data reports between 1,983 and 2,674 hospitalisations annually due to unruptured cerebral aneurysms over the same period. Therefore, it is proposed AIHW procedure numbers are likely indicative of the total proposed population.

Table 5 AIHW hospital statistics, 2011-12 to 2015-16

Procedure	2011-12	2012-13	2013-14	2014-15	2015-16
ACHI 9 th ed					
Endovascular occlusion of cerebral aneurysm or arteriovenous malformation	1,150	1,122	1,280	1,416	1,518
Clipping of cerebral aneurysm	874	900	913	838	833
Total	2,024	2,022	2,193	2,254	2,351
Principal diagnosis ICD-10-AM 9 th ed					
Cerebral aneurysm, nonruptured	1,983	2,080	2,249	2,318	2,674

Procedure data are linearly extrapolated out to 2022, Figure 4, for use in utilisation estimates in Q48 and Q49.

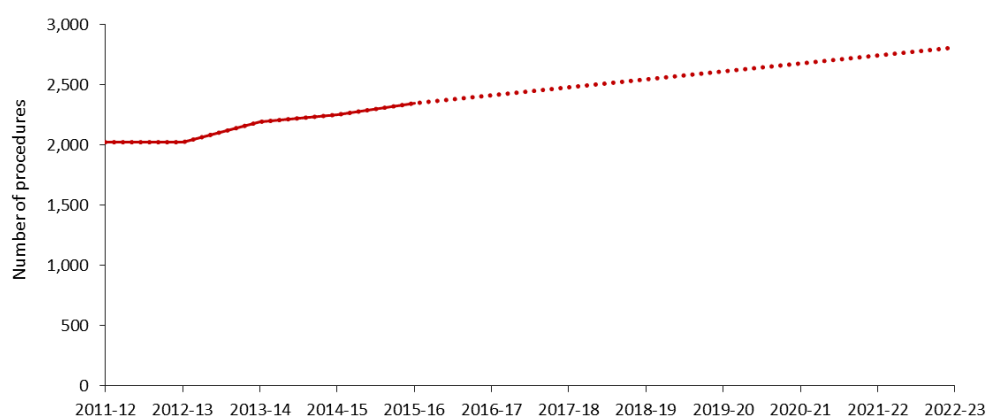


Figure 4 Projected procedures performed in Australian hospitals for the treatment of UIAs, 2011-2020

46. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

The objective of the treatment is to be a once off service. Endovascular insertion of FDDs is associated with an estimated reintervention rate of between 2.8–10.3% (Chalouhi et al 2013b; Chalouhi et al 2014; Chalouhi et al 2017). As such, a proportion of patients will access a second FDD endovascular service. Evidence in a population with aneurysms larger than 10 mm, suggests that retreatment rates are lower with FD compared to coiling (2.8% vs 36.7%; Chalouhi et al 2013b).

47. How many years would the proposed medical service(s) be required for the patient?

As stated in Q.46 FDD is to be a once off service. Any reinterventions are assumed to occur within the first-year post index treatment.

48. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:

The applicant estimates that approximately 400 procedures for the endovascular insertion of FDD were conducted in Australian hospitals in 2017. This reflects approximately 25% of total 1,628 endovascular occlusion procedures in 2017 based on the linear extrapolation presented in Figure 4. Current utilisation of FDD is expected to bias towards a public setting due to a lack of MBS and prosthesis list reimbursement. Post MBS and listing on the prosthesis list, the current FDD market share (25%) is expected to be distributed between private and public settings as is currently experienced in coiling and clipping procedures. Based on 2017 AIHW data, Medicare data and estimates, presented in Table 6, 38.6% of coiling and clipping procedures are performed in a private setting.

Table 6 Estimated distribution of UIA procedures between public and private settings

Row	Parameter	2017	Source
Endovascular coiling			
A	Endovascular occlusion of cerebral aneurysm or arteriovenous malformation – private and public	1,628	AIHW ^a
B	Endovascular FDD – private and public	400	Applicant
C	Endovascular coiling – private and public	1,228	A-B
D	Endovascular coiling – private only (MBS item 35412)	470	Medicare ^b
E	% performed in private setting	38.3%	D/C
Surgical clipping			
F	Clipping of cerebral aneurysm – private and public	872	AIHW ^a
G	Surgical clipping – private only (MBS items 39806 and 39800)	340	Medicare ^b
H	% performed in private setting	39.0%	G/F
Combined clipping and coiling			
I	Private and public	2,500	C+F
J	Private only	810	D+G
K	% performed in private setting	38.6%	I/J

^a AIHW: Procedure data cubes (ACHI 9th ed): linearly extrapolated out to 2017

^b Medicare statistics: http://medicarestatistics.humanservices.gov.au/statistics/pbs_item.jsp

Applying this distribution, 38.3%, and current FDD market share, 25%, to 2019 endovascular occlusion procedure estimates results in 168 FDD procedures being performed in a private setting in Year 1, Table 7. FDD market share in a private setting is expected to increase through the substitution of coiling and clipping procedures. In Year 1, it is estimated that 20% of MBS coiling and clipping procedures will be substituted by FDD due the availability of reimbursement and superior effectiveness, resulting in an additional 178 FDD procedures provided in a private setting. Substitution is expected to primarily comprise treatment of aneurysms ≥ 10 mm and aneurysms < 10 mm with complex anatomy (wide neck, fusiform, dysplastic). As a result, it is estimated that the proposed medical service will be utilised privately 346 times in Year 1 of listing.

Table 7 Estimated utilisation of endovascular FDD insertion in Year 1 (2019)

Row	Parameter	Year 1 (2019)	Source
Utilisation based on current market share			
A	Total endovascular occlusion procedures	1,776	AIHW ^a
B	% of endovascular occlusion procedures, FDD	25%	400/1,628
C	FDD procedures based on current utilisation	436	A*B
D	% performed in private setting	38.6%	Table 6
E	Total performed in a private setting	168	C*D
Additional utilisation post listing			
F	Total clipping and coiling procedures in private setting	890	Medicare ^b
G	% of clipping and coiling procedures substituted with FDD in private setting	20%	Assumption
H	FDD substituted from clipping and coiling	178	F*G
I	Total estimated utilisation of the proposed medical service via MBS	346	E+H

^a AIHW: Procedure data cubes (2011/12-2015/16) (ACHI 9th ed): linearly extrapolated out to 2022

^b Medicare statistics (2006-2017): linearly extrapolated out to 2022

49. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:

Estimates of utilisation through Years 2 to 4 of listing are estimated using the same approach as presented in Q48. Substitution from clipping and coiling procedures performed in a private setting is assumed to increase from 20% in Year 1, to 35% by Year 4. This incremental increase over the first few years of listing is applied to account for the learning curve associated with the listing of a new medical service.

Private utilisation of FDD procedures is expected to increase from 408 in Year 2 to 543 in Year 4, as presented in Please note, these estimates will be confirmed in a submission-based assessment (SBA).

Table 8. Please note, these estimates will be confirmed in a submission-based assessment (SBA).

Table 8 Estimated utilisation of endovascular FDD insertion in Years 2 to 4 (2020-22)

Parameter	Year 2 (2020)	Year 3 (2021)	Year 4 (2022)
Utilisation based on current market share			
Total endovascular occlusion procedures	1,849 ^a	1,923 ^a	1,996 ^a
% of endovascular occlusion procedures, FDD	25%	25%	25%
FDD procedures based on current utilisation	454	472	490
% performed in private setting	38.6%	38.6%	38.6%
Total performed in a private setting	175	182	189
Additional utilisation post listing			
Total clipping and coiling procedures in private setting	930 ^b	970 ^b	1,011 ^b
% of clipping and coiling procedures substituted with FDD in private setting	25%	30%	35%
FDD substituted from clipping and coiling	233	291	354
Total estimated utilisation of the proposed medical service via MBS	408	473	543

^a AIHW: Procedure data cubes (2011/12-2015/16) (ACHI 9th ed): linearly extrapolated out to 2022

^b Medicare statistics (2006-2017): linearly extrapolated out to 2022

PART 8 – COST INFORMATION

50. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

The provision of the proposed medical service, endovascular insertion of FDD, is estimated to cost \$23,103 for the treatment of UIA < 10mm) and \$25,042 for the treatment of UIAs ≥ 10mm. Cost estimates are comprised of; device (FDDs), FDD insertion, anaesthesia (initiation and time units), imaging (DSA) and consumable (catheters and microwires) costs. Table 9 provides breakdown of estimated procedure costs associated with the endovascular insertion of FDD.

Table 9 Costs associated with the endovascular insertion of FDD

Row	Parameter	< 10 mm aneurysms	≥ 10 mm aneurysms	Source/calculation
A	Mean FDDs per procedure	1.0	1.67	Chiu (2013) ^a
B	Cost per FDD	\$14,995		Applicant
C	Cost of FDDs per procedure	\$14,995	\$25,042	A*B
D	Cost of FDD insertion	\$2,857.55		MBS item 35412
E	Cost of anaesthesia ^b	\$574.20		MBS item 20216 and 23072
F	Cost of DSA ^c	\$1,376.30		MBS item 60009
G	Cost of consumables (catheters, microwires, etc)	\$3,300 ^d		Applicant
H	Total cost per procedure	\$23,103.05	\$25,042.00	C+D+E+F+G

^a FDD per patient estimates are based on cut-offs of <7 mm and >12 mm.

^b Assumed that all patients receive general anaesthesia. MSAC item 20216: Initiation of management of anaesthesia for intracranial vascular procedures including those for aneurysms or arterio-venous abnormalities. MSAC item 23072: 1:36 hours to 1:40 hours anaesthesia time units.

^c Assumed that all patients receive a DSA (digital subtraction angiography).

^d Introducer (1x \$300), Sheath (1x\$600), Guidewires (2x\$500), Distal access catheter (1x\$700) and Microcatheter (1x\$700)

51. Specify how long the proposed medical service typically takes to perform:

Park (2016) reported a mean treatment duration of 97 minutes (SD: 46.2) for the endovascular insertion of FDD alone. Park (2016) is an international retrospective study of the Pipeline Embolization Device registry and included the treatment of 797 aneurysms using FDD alone across 689 patients.

52. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

The proposed MBS item descriptor for endovascular insertion of FDD is an amendment of the existing item number for endovascular coiling. Given the management of patients with UIA is performed on a case by case basis, it is proposed the item descriptor allows flexibility for FDD as it does for coiling.

It is acknowledged that the current MBS item for endovascular coiling explicitly includes both ruptured and unruptured aneurysms, whilst the current application addresses the treatment of unruptured aneurysms with FDD. According to KOL feedback, FDD will rarely be used in the treatment of ruptured aneurysms, because FDD required dual antiplatelets post-procedure which may increase risk of bleeding.

Category 3 – THERAPEUTIC PROCEDURES

Proposed item descriptor:

Intracranial aneurysm, ruptured or unruptured, endovascular embolization, with parent artery preservation, not for use with liquid embolics only, including aftercare, including intra-operative imaging, but in association with the following pre-operative diagnostic imaging items:- either 60009 or 60010; and

- either 60072, 60073, 60075, 60076, 60078 or 60079

Fee: \$2,857.55 Benefit: 75% = \$2,143.20 85% = \$2,775.85

Appendix 1

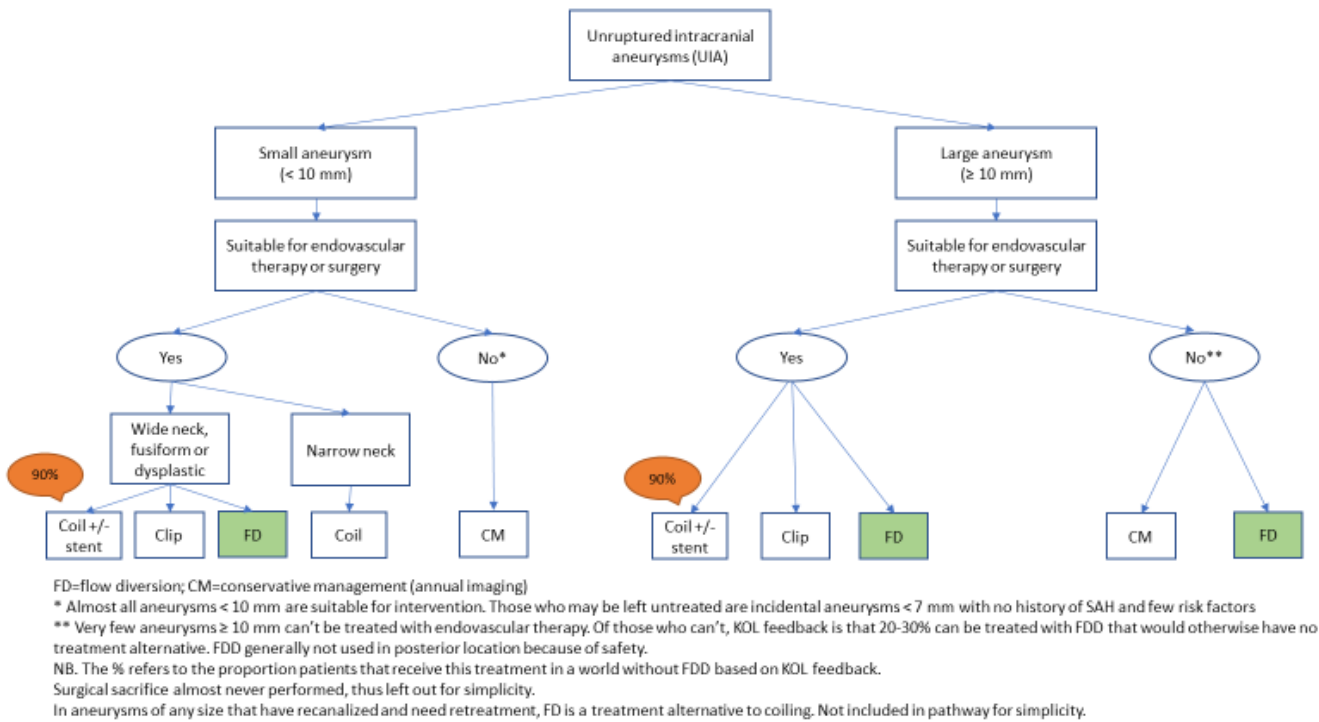


Figure 5 Clinical algorithm of UIAs

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PART 9 – FEEDBACK

The Department is interested in your feedback.

53. How long did it take to complete the Application Form?

N/A

54. (a) Was the Application Form clear and easy to complete?

N/A

- Yes
 No

(b) If no, provide areas of concern:

N/A

Describe areas of concern here

55. (a) Are the associated Guidelines to the Application Form useful?

N/A

- Yes
 No

(b) If no, what areas did you find not to be useful?

N/A

Insert feedback here

56. (a) Is there any information that the Department should consider in the future relating to the questions within the Application Form that is not contained in the Application Form?

N/A

- Yes
 No

(b) If yes, please advise:

N/A

Insert feedback here