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): N/A
Corporation name: Medtronic Australasia Pty Ltd
ABN: 47 001 162 661
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]

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

Transmural fixation of aortic endograft adjunct to endovascular aneurysm repair using helical anchors

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 aneurysm is defined as an artery that has localised dilatation more than 1.5 times greater than the usual diameter of that artery (Johnson et al 1991). When the aneurysm occurs in the aorta it is referred to as an aortic abdominal or thoracic aneurysm dependent on its location. Most aortic aneurysms occur in the abdomen (referred to as AAA) with thoracic aortic aneurysm (TAA) occurring less frequently.

Aortic aneurysms (AAs) are often asymptomatic and are often identified incidentally through imaging for symptoms unrelated to the AA. The natural history is ongoing expansion of the aneurysm, with the risk of rupture increasing with increasing size. Patients with a ruptured aneurysm have more than 50% risk of death before hospitalisation or treatment (Chaikof et al 2018). Whilst AA is rare in people < 50 years old, the prevalence increases sharply with increasing age with more men than women affected.

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 fixation of aortic endografts using helical anchors adjunctive to aortic endovascular aneurysm repair (EVAR) or thoracic endovascular aneurysm repair (TEVAR). Type IA endoleaks at the proximal attachment site and loss of fixation with endograft migration continue to pose a challenge in aortic aneurysm (AA) management. Current management of hostile aneurysm neck anatomy involve more complex EVAR/TEVAR procedures including fenestrated, chimney and branched endografts.

The introduction of the helical anchors used adjunct to EVAR/TEVAR represents an alternate treatment option for patients with complex aneurysms that have hostile neck anatomy, have experienced or are at risk of a type IA endoleak or device migration or late graft failure. Helical anchors adjunct to EVAR/TEVAR is intended specifically to aid in the sealing and fixation of endografts potentially reducing revision procedures and re-hospitalisations; and potentially introducing costs savings when compared with complex AAA/TAA stent graft systems.

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:

N/A

(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):

N/A

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

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)*:

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):

N/A

(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):

N/A

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

Single use consumables: Heli-FX Applier; Heli-FX Guide with Obturator (consists of a steerable catheter and control handle)
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: EndoAnchor system
Manufacturer's name: Medtronic Vascular 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)
☐ No

ARTG number	Product description	Intended purpose	Sponsor
283911	**The Aptus Heli-FX EndoAnchor System** is comprised of an endovascular suture (the EndoAnchor) and implantation means (the Heli-FX Applier) as well as a steerable guide sheath (the Heli-FX Guide) for access and delivery within the vasculature	The Aptus Heli-FX EndoAnchor System (to be deployed in the abdominal aorta) is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The Aptus Heli-FX EndoAnchor System is indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion	Medtronic Australasia Pty Ltd
283912	**The Aptus Heli-FX Thoracic EndoAnchor** System is comprised of an endovascular suture (the EndoAnchor) and an implantation means (the Heli-FX Applier) as well as a steerable guide sheath (the Heli-FX Guide) for access and delivery within the vasculature	The Aptus Heli-FX Thoracic EndoAnchor System (to be deployed in the thoracic aorta) is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The Aptus Heli-FX EndoAnchor System is indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented radial fixation and/or sealing is required to regain or	Medtronic Australasia Pty Ltd

ARTG number	Product description	Intended purpose	Sponsor
		maintain adequate aneurysm exclusion	
298952	**The Aptus Heli-FX EndoAnchor System** is comprised of an endovascular suture (the EndoAnchor) and implantation means (the Heli-FX Applier) as well as a steerable guide sheath (the Heli-FX Guide) for access and delivery within the vasculature	The Aptus Heli-FX EndoAnchor System (to be deployed in the abdominal aorta) is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The Aptus Heli-FX EndoAnchor System is indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion	Medtronic Australasia Pty Ltd
298953	**The Heli-FX Thoracic EndoAnchor System** is comprised of an endovascular suture (the EndoAnchor) and an implantation means (the Heli-FX Applier) as well as a steerable guide sheath (the Heli-FX Guide) for access and delivery within the vasculature	The Heli-FX Thoracic EndoAnchor System (to be deployed in the thoracic aorta) is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The Heli-FX EndoAnchor System is indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion.	Medtronic Australasia Pty Ltd

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

17. **Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (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 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.	ANCHOR is a single-arm prospective, multicentre, multinational study.	One-year results of the ANCHOR trial of EndoAnchors for the prevention and treatment of aortic neck complications after endovascular aneurysm repair.	The study included 100 patients with one-year follow-up. The primary cohort (N = 73) comprised patients who underwent EndoAnchor implantation at the time of an initial EVAR and the Revision cohort (N = 27) included previously treated with EVAR. A total of 6 patients (6%) had aneurysm-related reintervention over 18 months of clinical follow-up. There were no aneurysm ruptures. Freedom from type IA endoleak was 95% in the Primary Arm and 77% in the Revision Arm (P =0.006). Aneurysm sacs regressed > 5 mm within one year in 45% of the Primary cases and in 25% of the Revision cohort. Despite a high frequency of hostile neck anatomy, proximal neck complications were relatively infrequent after EndoAnchor use.	https://www.ncbi.nlm.nih.gov/pubmed/26069087?dopt=Abstract Nb. The ANCHOR registry is published multiple times, including: https://www.ncbi.nlm.nih.gov/pubmed/25809354?dopt=Abstract https://www.ncbi.nlm.nih.gov/pubmed/25088739?dopt=Abstract	Jordan 2016 Jordan 2015 Jordan 2014
		Analysis of	During a 2-year follow-up, 319 patients	https://www.ncbi.nlm.nih.gov/pubmed/25284629	De Vries 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***
		EndoAnchors for endovascular aneurysm repair by indications for use	were enrolled in the ANCHOR study including patients undergoing EVAR for the first time (primary arm n=242) and those with requiring revision at a separate time from initial EVAR (revision arm, n=77). During a median imaging follow-up of 7 months, 90.1% remained free of type IA endoleaks. Primary prophylactic patients were free from type IA endoleak in 110 of 114 cases (96.5%). The most challenging subset was revision patients treated for type IA endoleak; type IA endoleaks were evident during follow-up in 10 of 29 of the cases (34%). Sac regression >5 mm in patients with 1-year imaging was observed in 39% (26/66) and was highest in the primary prophylaxis subset (20/43; 47%).		
2.	Propensity score matched cohorts study	Matched cohort comparison of endovascular abdominal aortic aneurysm repair with and without EndoAnchors	Freedom from type IA endoleak was 97.0% in the ANCHOR cohort vs 94.1% in EVAR alone control cohort through 2 years. The 2-year freedom from neck dilation (90.4% vs 87.3%) and freedom from sac enlargement (97.0% and 94.0%) was similar in the ANCHOR and control cohorts respectively. No device migration was observed. A significantly	https://www.ncbi.nlm.nih.gov/pubmed/29248241	Muhs 2018

#	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***
			higher proportion of ANCHOR subjects had aneurysm sac regression through 2 years compared with control subjects (81.1% ± 9.5% vs 48.7% p = 0.01).		
3	Prospective, multicentre, single-arm investigational device exemption trial	Outcome of the pivotal study of the Aptus endovascular abdominal aortic aneurysms repair system	A total of 155 patients with AAA were enrolled across 25 sites in the US. Eligibility criteria included proximal neck length of ≥12 mm, diameter of 19-29 mm, and infrarenal angulation of≤ 60 degrees. Overall, the primary safety (freedom from major adverse events at 30 days) and effectiveness (successful aneurysm treatment at 12 months) end points were met in 98.1% and 97.4% of the subjects, respectively. Aneurysm-related mortality was 0.6%, and there were no AAA ruptures.	https://www.ncbi.nlm.nih.gov/pubmed/25064325	Mehta 2014
4.	Consecutive, case series	The use of EndoAnchors in repair EVAR cases to improve proximal endograft fixation.	A total of 11 patients were treated with EndoAnchor for failed primary endograft. During a mean follow-up of 10 months no EndoAnchor-related complications or renewed migration of the endografts occurred. Two patients underwent repeat intervention due to persistent type IA endoleak during follow-up.	https://www.ncbi.nlm.nih.gov/pubmed/22854521	Avci 2012

** 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, including providing the trial registration number to allow for tracking purposes.*

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

EVAR=endovascular aortic aneurysm repair.

18. 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.	There are no yet to be published research identified. The ANCHOR registry is however ongoing and listed on Clinicaltrils.gov.				

** 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).*

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

19. **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 and New Zealand Society for Vascular Surgery(ANZSVS) and Royal Australasian College of Surgeons (RACS)

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

    The comparator services are provided by the same health care professionals, i.e. vascular surgeons, so there are no professional bodies/organisations that may be impacted by the proposed medical service.

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

    No known consumer groups exist

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

    No other sponsors or manufacturers produce similar devices to the helical anchors

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

    Name of expert 1: [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

24. 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:

An aneurysm is defined as an artery that has localised dilatation more than 1.5 times greater the usual diameter of that particular artery (Johnson et al 1991). When the aneurysm occurs in the aorta it is referred to as an aortic abdominal or thoracic aneurysm dependent on its location. Most aortic aneurysms occur in the abdomen (referred to as AAA) and are diagnosed when the diameter of the abdominal aorta is > 30 mm. Thoracic aortic aneurysm (TAA) is defined as having a diameter > 40 mm (Department of Health Western Australia [DoH WA] 2008).

Most aneurysms are caused by a breakdown in the protein that provides structural strength of the vessel wall. This breakdown of protein in part occurs with increasing age, however these processes may be accelerated by smoking, high blood pressure and atherosclerotic inflammation in younger people (DoH WA 2008).

Most patients diagnosed with an AAA are asymptomatic. That is, the AA was detected incidentally from imaging for unrelated symptoms. However, some patients present with abdominal or back pain which may be due to an unruptured or ruptured AAA – these cases are considered acute and require prompt treatment. Patients with a ruptured aneurysm have more than 50% risk of death before hospitalisation or treatment (Chaikof et al 2018).

Most AAAs are fusiform, and some are saccular in shape (Chaikof et al 2018). A fusiform aneurysm bulges out on both sides of the aorta without a distinct neck whereas the saccular aneurysm has a berry like presentation and a distinct neck.

Whilst AA is rare in people < 50 years old, the prevalence increases sharply with increasing age with more men than women affected. AA is estimated to affect 4-7% of men and 1-2% of women aged 65 years or older. Risk factors for AA includes smoking, male gender, increasing age, hypertension and family history. Risk of rupture increase when the aneurysm enlarges. Generally, aneurysms greater than 5.5 cm in diameter require repair (Erbel et al 20145; Chaikof et al 2018).

Maximum AAA diameter is the most widely utilised and validated parmeter for prediction of rupture risk (Chaikof et al 2018). The natural history is ongoing expansion of the aneurysm, with the risk of rupture increasing with increasing size. Based on a retrospective review of 24,000 consecutive autopsies performed during 23 years at a single institution, it was found that 118 of the 473 non-resected AAAs (25%) identified in this series were ruptured. Approximately 40% of AAAs >5 cm in diameter were ruptured, although 40% of AAAs between 7 and 10 cm were unruptured. Of AAAs < 5 cm 13% were ruptured (Darling et al 1977). The rupture risk per year by AAA diameter is increasing with size (Table 1).

Table 1 Yearly rupture risk of AAA by diameter

AAA diameter (cm)	Risk of rupture (%/year)
3.0-3.9	0%
4.0-4.9	1%
5.0-5.9	1-10%
6.0-6.9	10-22%
7.0	30-50%

Source: Lederle et al. 2002

25. 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:

Patients with asymptomatic AAs may be identified through screening or incidentally from imaging for unrelated symptoms. There are currently no formal screening programs for AAA in Australia (Robinson et al 2013). At the time of diagnosis, patients may be referred to a vascular surgeon for advice, counselling regular surveillance imaging. When the size of the AAA is approaching 4 cm, patients should be referred to a vascular surgeon for consideration of surgery.

Patients with known AAA presenting with symptoms such as abdominal or back pain, syncope or tenderness over the aneurysm area, should be assessed promptly by a vascular surgeon for surgery (Robinson et al 2013). Patients with ruptured aneurysms need to be transferred immediately to an operating room for definitive repair (Chaikof et al 2018). The goal is for acute patients, those presenting with symptoms or ruptured aneurysm, to receive intervention within 90 minutes of presenting to the emergency department or first medical contact (Chaikof et al 2018).

A ruptured AA is a major emergency. Generally, the closer the location of the aneurysm to the aortic valve, the greater the risk of death. Less than half of all patients with rupture arrive at hospital alive (Erbel et al 2014) with an overall mortality rate of 80-90% (Bengtsson et al 1993). This high risk of death highlights the need for prompt treatment in patients presenting with symptoms of rupture.

The SVS recommend ultrasound for screening and surveillance of AAs, and computed tomography angiography (CTA) for deriving the maximum aneurysm diameter, based on an outer wall to outer wall measurement perpendicular to the aorta. CTA is the mainstay imaging used for pre-procedural planning (Chaikof et al 2018; Robinson et al 2013).

As discussed in detail in Q.26, the main treatment options include open repair and EVAR/TEVAR. EVAR/TEVAR is the preferred treatment option generally by vascular surgeons, given it is minimally invasive and associated with lower risk of operative mortality which however comes at the expense of higher re-intervention rate. Most reinterventions are related to late graft endoleaks and/or stent migrations.

EVAR/TEVAR are associated with a long-term risk of endoleaks. An endoleak is the persistent blood flow in the aneurysm sac after EVAR/TEVAR, that is, flow outside the stent-graft but within the aneurysm sac. An endoleak may be identified at the time of EVAR or may take months to develop and as such lifelong surveillance after EVAR/TEVAR is required (Chaikof et al 2018). Endoleaks are usually asymptomatic and may be identified during routine follow up imaging, ultrasound or CTA after EVAR/TEVAR.

There are five types of endoleaks (I-V; Table 2) with types I and III considered failures and requiring treatment (Erbel et al 2014). A type IA endoleak occurs when there is an incomplete seal between the graft and the vessel wall at seal zones, at the proximal aortic attachment site (type IA) or at the distal iliac attachment site (IB). The incomplete seal allows blood flow outside the graft and into the aneurysm sac, resulting in an increased sac pressure which in turn increases risk of rupture. Type IA endoleaks most commonly occur in aneurysm with short or severely angulated neck, or a reverse tapered neck or in the case of substantial calcification or thrombus at the attachment site. A delayed type IA endoleak occur if the device migrates into the aneurysm sac (Chaikof et al 2018).

The standard EVAR/TEVAR grafts (tube or bifurcation graft) are not suitable for treatment of aneurysms with more hostile neck anatomy. “Hostile” neck anatomy is defined as any of the following: length < 10 mm, diameter > 28 mm, angulation > 60 degrees or aortic neck is conical (de Vrieset al 2014). These aneurysms require complex EVAR/TEVAR grafts, including fenestrated, branched or chimney grafts, to overcome the challenges associated with the hostile anatomy. Therefore, treatment decisions depend on level of hostility of the aneurysm neck.

The fixation of the endograft using helical anchors adjunct to standard EVAR/TEVAR will provide an alternate treatment option for aneurysms at risk of endoleaks or stent migration such as hostile neck anatomy, that is less complex than fenestrated, branched or chimney EVAR/TEVAR. Some complex grafts are custom made, taking several weeks to produce. In contrast helical anchors are off the shelf, allowing immediate treatment of patients.

Table 2 Classification of endoleaks

Type	Explanation
Type I	Leak at graft ends (inadequate seal) IA: proximal IB: distal IC: iliac occlude [most common after TAA]
Type II	Sac filling via branch vessel (e.g. lumbar or inferior mesenteric artery) IIIA: single vessel IIB: two vessels or more [most common after repair of AAA (80%), sometimes referred to as a "retroleak", most type II endoleaks spontaneously resolve and require no treatment]
Type III	Leak through a defect in graft fabric (mechanical failure of graft) IIIA: junctional separation of the modular components IIIB: fractures or holes involving the endograft
Type IV	A generally porous graft (intentional design of graft)
Type V	Endotension [Not a true leak but is defined as continued expansion of the aneurysm sac > 5 mm, without radiographic evidence of a leak site]

Source: https://radiopaedia.org/articles/classification-of-endoleaks (accessed 6/7/18).

In the proposed medical service, the helical anchors are fixed in the proximal aortic attachment, thus improving the seal between the graft and the native vessel. As such, the proposed service will provide an alternate treatment option for aneurysms with high risk of Type IA endoleaks in prophylactic and revision settings.

Despite the low re-intervention rate of open repair, some patients with repaired aneurysms experience late graft failure and require revision. A retrospective cohort study by von Segesser et al (2014) investigated the usefulness of endovascular surgery for repair of aortic lesions late after open surgical repair. In this cohort the mean interval between open surgery and endovascular repair was 9 ± 8 years indicating the lateness of such events. The fixation of helical anchors adjunct to EVAR in these patients represent an alternate to repeat open surgery or standard EVAR/TEVAR.

Consistent with the clinical pathway as described in Q26 and expressed clinical need by key opinion leader (KOL), the proposed populations for fixation of graft using helical anchors adjunct to EVAR/TEVAR for the treatment of AA are as follows:

Population 1: Prophylactic/acute repair in patients at risk of Type I endoleaks with hostile neck anatomy

Population 2: Therapeutic (revision) treatment to resolve Type IA endoleaks/device migration after EVAR/TEVAR

Population 3 Therapeutic (revision) treatment to resolve late graft failure (Type IA endoleaks) after open repair, where proximal fixation/sealing is indicated.

26. 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):

Overview of clinical management

The proposed service, fixation of aortic endograft as adjunct to EVAR/TEVAR using helical anchors, is used in the repair of AAAs and TAAs. The current clinical management of AAA/TAA is informed by two recently published international guidelines, the US Society for Vascular Surgery (SVS; Chaikof et al 2018) and the Task Force for the Diagnosis and Treatment of Aortic Diseases of the European Society of Cardiology (ESC) guidelines (Erbel 2014). It should be noted that the NICE guidelines for 'abdominal aortic aneurysm:

diagnosis and management' are in the process of being updated and are currently open for consultation. These guidelines are expected to be finalised in November 2018 and will replace NICE technology appraisal guidance 167 (published February 2009). The NICE guidelines are not summarised within this section.

A summary of the US SVS and ESC guidelines in relation to which aneurysms should be treated and which treatment option is suitable is provided in Table 3.

AAA

The guidelines consistently recommend treatment of an AAA that is > 5.5 cm (cut off 5.4 cm in SVS guidelines) with smaller aneurysm managed conservatively through monitoring. SVS recommends treatment of all saccular aneurysm irrespective of size.

Both the SVS and ESC guidelines favour EVAR over open repair in patients with AAA suitable for EVAR, given the significantly lower risk of operative mortality. Both guidelines acknowledge that this benefit of EVAR relative to open repair is lost during follow-up and EVAR is also associated with a higher re-intervention rate. Both guidelines concur that in AAAs unsuitable for EVAR, open repair remains the reference standard. The SVS guidelines suggest that fenestrated, branched, chimney or snorkel EVARs may be used in those with more complex anatomy.

In relation to management of endoleaks, Type I and Type III endoleaks require correction (Erbel 2014; Chaikof 2018). ESC recommends Type I and Type III endoleaks be corrected using proximal cuff or extension. For Type IA endoleaks, the SVS recommend initial management using angioplasty with a compliant balloon, followed by extension cuff placement. Additional procedures may include placement of a balloon-expandable stent or endostapling (such as helical anchors). Conversion to open repair is only recommend if there is a rupture or significant device maldeployment. In the case of a persistent Type IA endoleak, treatment options include the placement of a fenestrated device, proximal cuff extension with chimney grafts to the renal arteries, external banding, embolization with coils or glue, or conversion to open surgery. The SVS does not favour any particular strategy given insufficient data.

TAA

Whilst the ESC guidelines cover management of TAA, the SVS guidelines do not. Treatment of TAA depends on location, ascending, aortic arch or descending. Dependent on size, location and comorbidities, surgery is broadly indicated in aneurysms located in the ascending aorta or in the aortic arch. TEVAR is indicted in aneurysm located in the descending aorta with suitable anatomy with maximal diameter ≥ 5.5 cm. Endoleaks may also occur following TEVAR in TAA, with Type I and III considered treatment failures requiring additional treatment (cuffs or extension) to prevent risk of rupture (Erbel 2014).

Acute treatment - symptomatic or ruptured aneurysms

The SVS and ESC guidelines recommend endovascular repair in patients with ruptured aneurysms (Chaikof et al 2018; Erbel et al 218). These patients may present with symptoms or have a history of rupture, and given the high mortality risk, should receive intervention within 90 minutes from presenting to the emergency department (Chaikof et al 2018). Typical presentation of ruptured AAA includes acute abdominal pain, hypotension, abdominal pulsatile mass and shock. Symptoms of contained ruptured include abdominal and back pain (Chaikof et al 2018; Erbel et al 218).

Table 3 Summary of SVS and ESC treatment guidelines for aortic aneurysm repair

	SVS	**ESC**
AAA		
Indication for treatment	• We recommend repair for the patient who presents with an AAA and abdominal or back pain that is likely to be attributed to the aneurysm. • We recommend elective repair for the patient at low or acceptable surgical risk with a fusiform AAA that is ≥ 5.5 cm.	• AAA > 5.5 cm • Aneurysm growth > 10 mm/year

	SVS	ESC
	• We suggest elective repair for the patient who presents with a saccular aneurysm. • We suggest repair in women with AAA between 5.0 cm and 5.4 cm in maximum diameter. • In patients with a small aneurysm (4.0 cm to 5.4 cm) who will require chemotherapy, radiation therapy, or solid organ transplantation, we suggest a shared decision	
Choice of treatment	• OR of an AAA continues to be used for patients who do not meet the anatomic requirements for endovascular repair, including short or angulated landing zones, excessive thrombus, multiple large accessory renal arteries, and small and tortuous access vessels with concomitant occlusive disease. • Fenestrated, branched, and chimney or snorkel grafts have expanded the range of complex aortic anatomy potentially treatable by EVAR. • OR may be required for treatment of a persistent endoleak and aneurysm sac growth after EVAR or for treatment of a mycotic aneurysm or infected graft. • We suggest that elective EVAR be performed at centres with a volume of at least 10 EVAR cases each year and a documented perioperative mortality and conversion rate to OSR of 2% or less. • Open repair is recommended if endovascular intervention fails to treat a type I endoleak with ongoing aneurysm enlargement	• If a large aneurysm is anatomically suitable for EVAR, either open or endovascular aortic repair is recommended in patients with acceptable surgical risk • If a large aneurysm is unsuitable for EVAR, open aortic repair is recommended • In patients with asymptomatic AAA who are unfit for open repair, EVAR along with best medical treatment may be considered
Type I endoleaks	• Initial management is angioplasty with a compliant balloon, followed by extension cuff placement. Additional manoeuvres include placement of a Palmaz (Cordis, Bridgewater, NJ) balloon-expandable stent or endostapling. • Conversion to open repair is not recommended unless rupture or significant, uncorrectable device maldeployment is noted. • A persistent type IA endoleak may be treated by placement of a fenestrated device, proximal cuff extension with chimney grafts to the renal arteries external banding, embolization with coils or glue, or conversion to open	• Type I endoleaks to be corrected using proximal cuff or extension

	SVS	ESC
	surgery.	
TAA		
Aortic root/ ascending aneurysms	–	Surgery is indicated in patients who have aortic root aneurysm with maximal aortic diameter ≥ 50 mm for patients with Marfan Syndrome
	–	Surgery should be considered in patients who have aortic root aneurysm, with maximal ascending aortic diameters • ≥ 45 mm for patients with Marfan Syndrome with risk factors • ≥ 50 mm for patients with bicuspid valve with risk factors • ≥ 55 mm for other patients with no elastopathy
	–	Lower thresholds for intervention may be considered according to body surface area in patient of small stature or in the case of rapid progression, aortic valve regurgitation, planned pregnancy, and patient's preference
Aortic arch aneurysms	–	Surgery should be considered in patients who have isolated aortic arch aneurysm with maximal diameter ≥ 55 mm.
	–	Aortic arch repair may be considered in patients with aortic arch aneurysm who already have an indication for surgery of an adjacent aneurysm located in the ascending or descending aorta.
Descending aortic aneurysms	–	TEVAR should be considered, rather than surgery, when anatomy is suitable
	–	TEVAR should be considered in patients who have descending aortic aneurysm with maximal diameter ≥ 55 mm.
	–	When TEVAR is not technically possible, surgery should be considered in patients who have descending aortic aneurysm with maximal diameter ≥ 60 mm
	–	When intervention is indicated, in cases of Marfan syndrome or other elastopathies, surgery should be indicated rather than TEVAR.
Ruptured aneurysm		
	If it is anatomically feasible, we recommend EVAR over open repair for treatment of a ruptured AAA	In patients with suspected rupture of AAA, immediate abdominal ultrasound or CT is recommended
		In case of ruptured AAA, emergency repair is indicated
		In case of symptomatic but non-ruptured AAA, urgent repair is indicated
		In case of symptomatic AAA anatomically suitable for EVAR, either open or endovascular aortic repair is

	SVS	ESC
		recommended[a]

Source: ESC guidelines (Erbel et al 2014); SVS guidelines (Chaikof et al 2018)

[a] Depending on the expertise of the interventional team and patient's level of risk.

Details of treatment options

Open repair

Open surgical repair of AA is involves clamping the aorta to stop blood flow, opening the aneurysm to remove thrombus and debris from within the aorta, and suturing a synthetic graft to replace the diseased arterial segment. The procedure is performed under general anaesthesia and the patients is monitored for volume status. Fluid administration and transfusion is administered as required. The effectiveness and durability of repair is well established for open repair (Conrad et al 2007). However, given the invasiveness of the procedure, open repair is associated with perioperative mortality. The perioperative mortality in 1302 non-ruptured open repairs of AAAs in the first two years of the Australasian vascular Audit (2010-11) was 2.7% (Australasian vascular Audit reports 1/2010 and 2/201 and 2011 cited in Robinson et al 2013).

EVAR/TEVAR

EVAR/TEVAR is a medical procedure designed to reinforce the internal lining of the aorta using an endograft (England and Williams 2011). EVAR/TEVAR is preformed to exclude an aortic lesion from the circulation by means of implanting of a membrane-covered stent-graft across the lesion to prevent further expansion and rupture of the aneurysm. Careful pre-procedural planning using CTA is required.

For EVAR/TEVAR an appropriately sized stent-graft should be selected to ensure the diameter exceeds the reference aortic diameter at the landing zoned by at least 10-15% (Erbel 2014). The stent-graft is introduced from the ipsilateral side, using a guide wire, with the contralateral access used for a pigtail catheter for intraprocedural angiography. After reaching the target position, in the case of TEVAR the blood pressure is reduced (pharmacologically or using rapid right ventricular pacing), to prevent downstream displacement, and the graft is then deployed. The EVAR can be performed using general or conscious sedation (Erbel 2014).

Not all aortic aneurysms are anatomically suitable for standard EVAR/TEVAR stent grafts. That is, for EVAR/TEVAR to be performed successfully, an adequate sealing zone above and below the AA, and adequate access vessels (common femoral and iliac) and relationship to side branches to accommodate the large stent graft delivery system are required (Robinson 2013, Erbel 2014). For EVAR, the proximal aortic neck (the healthy aortic segment between the lowest renal artery and the most cephalad extent of the aneurysm) should have a length of at least 10–15 mm and should have a diameter ≤ 32mm, and a neck angulation of < 60 degrees (angulation greater than 60 degrees increases risk of device migration and endoleaks; Erbel 2014, Chaikof 2018). For TEVAR, the proximal and distal landing zones should have a diameter < 40 mm and length ≥ 20 mm (Erbel 2014).

Endografts come in a variety of structural forms, designed to suit the anatomy surrounding the site of aneurysm. Many of the available endografts are not suitable or indicated (based on directions for use) for patients with aneurysm with hostile neck anatomy. Types of endograft include; tube, bifurcated, fenestrated, branched and chimney/snorkel. The bifurcated graft allows for implantation across the aortic bifurcation as part of standard EVAR. For this Application, tube and bifurcated grafts are used in a 'standard EVAR/TEVAR', whereas fenestrated, branched or chimney grafts are used in 'complex EVAR/TEVAR'. The complex EVAR/TEVAR are used in in AAAs/TAAs with more complex anatomy where sealing zone above and below the AA is inadequate a standard endograft and the aneurysm neck anatomy is considered hostile. Details of the complex grafts are provided below.

Fenestrated graft

Fenestrated grafts were developed to provide an endovascular treatment option for patients with AAAs whose aneurysm necks are anatomically unsuitable for repair with standard grafts. The fenestrated graft (such as Zenith) has fenestrations that allows flexing of the graft to align with the branching of arteries. Fenestrated grafts are custom made devices using computed tomography (CT) based on the exact

location of the visceral arteries in the individual patient. The deployment of fenestrated grafts is more complex than the deployment of standard endografts. Specific complications may occur as a result of incorporating the visceral arteries in the repair. (Scurr and McWilliams et al 2007; Figure 1). Because the production of a fenestrated endograft is individually customised, it takes several weeks to produce. Consequently, the fenestrated graft is not used in the acute treatment of ruptured aneurysms or patient with symptoms of rupture (de Niet et al 2016).

Branched graft

A branched graft, as the name suggests has one or more branches to accommodate branching artery anatomy, as illustrated in Figure 1. In this procedure, a cuffed or fenestrated stent-graft forms the trunk and separately inserted covered stents form the branches of a branched thoracoabdominal stent-graft (Sweet et al 2009). Often various proximal and distal extensions are added to accommodate the anatomy of the patient. Branched grafts are often custom made and takes several weeks to produce, although some off-the-shelf grafts exist (t-branch; Cook Medical, Bloomington, In) (Gallitto et al 2017; Sweet et al 2009). Given the lengthy production time of custom made branched grafts, these are not used in the emergency setting.

Chimney graft

Chimney endografts (also referred to as snorkel or parallel grafts) may be used as an alternate to fenestrated endografts in aneurysms with challenging anatomy, especially in emergent cases. As illustrated in Figure 2, the procedure involves insertion of a stent parallel to the main endograft, protruding somewhat proximally like a chimney or a snorkel to allow blood flow to a vital side branch otherwise covered by the aortic endograft (Ohrlander et al 2008). Unlike the fenestrated endograft which is custom made and takes several weeks to produce, the chimney graft enables the use of standard, off-the-shelf grafts in urgent cases.

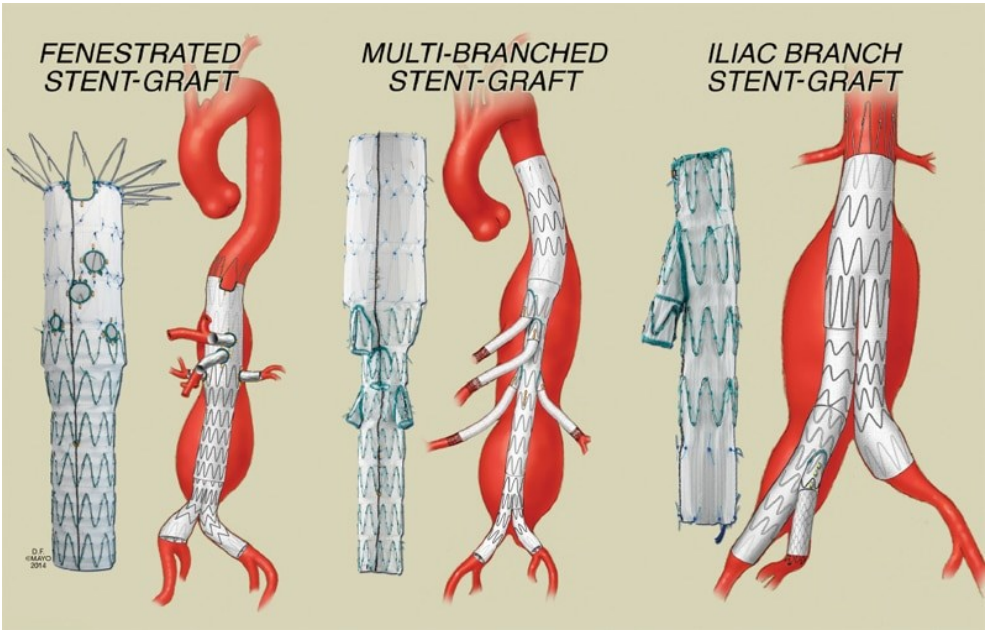

Figure 1 Fenestrated and branched grafts

Source: https://www.mayoclinic.org/medical-professionals/clinical-updates/cardiovascular/endovascular-repair-of-complex-aortic-aneurysms (accessed 4/7/18)

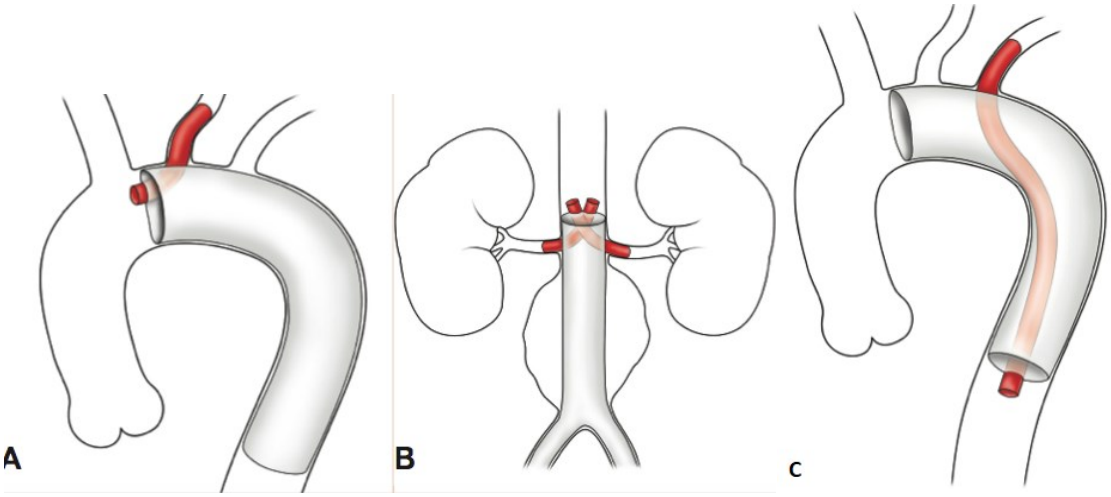

Figure 2 Single short left common carotid artery chimney (A), bilateral renal artery chimneys (B), long periscope chimney graft for the left subclavian artery (C)

Source: https://www.vasculardiseasemanagement.com/content/parallel-grafts-perspective-definitions-and-new-classification (accessed 4/7/18)

Revision EVAR/TEVAR

In a proportion of EVAR/TEVAR, endoleaks will be observed at the time of the procedure or post-procedure. There are five different types of endoleaks, of which Type I and III are considered treatment failures and require revision. Type I endoleaks may be observed intraoperatively or post operatively. Intraoperatively identified type I endoleaks are managed at the time of the procedure though angioplasty followed by extension cuff placement. Type I post-procedure endoleaks are managed in a similar way by a revision EVAR/TEVAR including the addition of components including cuffs, extenders or converters, or repositioning of stent graft and/or aggressive ballooning.

Clinical management pathway

The proposed clinical management pathway of AAA/TAA before patients would be eligible for the proposed medical service is informed by the SVS and ESC guidelines. KOL input was also sought to establish the management of AAA/TAA specifically in Australia and identify patients in whom there is a high clinical need for the proposed medical service. The resultant pathway is provided in Appendix A. Consistent with advice from KOL, management of acute (symptomatic and ruptured) and elective treatment of AAA and TAA is addressed in one algorithm.

Patients suitable for elective treatment, that is those with AAA or TAA ≥ 5.5 cm, will follow a different pathway based on the existence of hostile neck anatomy. Hostile neck anatomy is defined as length < 10 mm, diameter > 28 mm, or angulation > 60 degrees (De Vries et al 2014) and according to KOL feedback is present in 15-20% of cases. Most patients with hostile neck anatomy in Australia undergo a complex EVAR/TEVAR, which may include a fenestrated, chimney or branched graft. Based on KOL feedback fenestrated is the most commonly used complex EVAR. Chimney EVAR is used for acute cases presenting with symptoms of rupture or with rupture, given insufficient time is available for the customisation of the fenestrated graft.

Open repair is used in a small proportion of AAA/TAA patients, estimated at 5-10%. EVAR/TEVAR with adjunct transmural fixation of endograft using helical anchors provides an alternate treatment option in patients at risk of Type 1 endoleaks or with hostile neck as this procedure aids in the sealing and fixation of endografts in turn reducing the risk of endoleaks.

Endoleaks are observed in a proportion of aneurysm following EVAR/TEVAR. Endoleaks may be observed intraoperatively or post operatively. Whilst type III endoleaks may be managed through revision EVAR/TEVAR, Type I endoleaks may be managed either by revision EVAR/TEVAR or by the addition of

helical anchors for Type IA endoleaks. Type II endoleaks may be conservatively managed through monitoring of aneurysm growth, or open repair or through vessel embolization.

Open repair may result in late graft failure (intraoperative failure = death). It may take 5-10 years for the late graft failure to become apparent. Patients with late graft failure following open repair may undergo revision EVAR/TEVAR, repeat open repair or have EVAR/TEVAR with adjunct helical anchors.

In short, there are three distinct populations for which there is a clinical need for transmural fixation of endograft with helical anchors, as follows:

Population 1:	Prophylactic/acute repair in patients at risk of endoleaks and/or stent migration with hostile neck anatomy
Population 2:	Therapeutic treatment to resolve Type IA endoleaks/device migration after EVAR/TEVAR
Population 3	Therapeutic treatment to resolve late graft failure (Type IA endoleaks) after open repair

PART 6b – INFORMATION ABOUT THE INTERVENTION

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

Transmural fixation of endograft to the aorta adjunct to EVAR/TEVAR using helical anchors is performed at the same time as EVAR/TEVAR to improve the seal and fix the graft in place for at risk patients or added after the index EVAR/TEVAR in the case of type I endoleak. There is currently only one type of helical anchors indicated for the treatment of AAAs/TAAs registered for use in Australia, that is the EndoAnchor system, as such this section pertains specifically to this system.

The EndoAnchor is a "helical-like" metal alloy that is stapled through the deployed endograft, thereby augmenting the opposition with the aortic wall by mimicking a surgically sutured anastomosis. It is essentially a mechanical suture to be used in conjunction with EVAR (or TEVAR) to fix the graft in place.

The Aptus Heli-FX EndoAnchor System is comprised of an endovascular suture (the EndoAnchor each 4.5 mm in length, 3 mm in diameter) and implantation means (the Heli-FX Applier) as well as a steerable guide sheath (the Heli-FX Guide) for access and delivery within the vasculature. The EndoAnchors are supplied in a cassette of 10 (Figure 3). The Heli-FX system is available in both abdominal and thoracic variants.

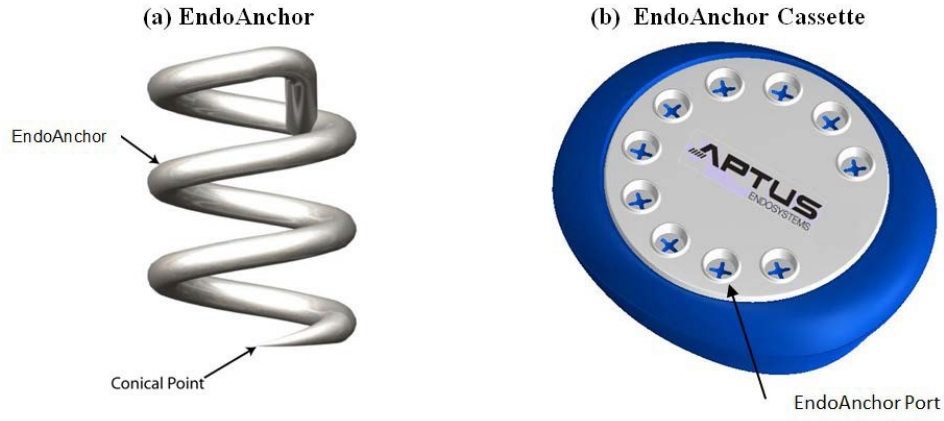

Figure 3 EndoAnchor and EndoAnchor cassette

EndoAnchors are implanted following deployment of the endograft. The basic implantation procedure is the same regardless of the Heli-FX system used (abdominal or thoracic), the type of endograft being anchored and whether the EndoAnchors are implanted during the primary endograft implantation (primary implantation) or at a later secondary intervention (revision).

Access to the vasculature is in the standard method for endovascular procedures. The Heli-FX Guide is inserted over a guide wire and its Obturator is positioned near the end of the endograft to be anchored, under fluoroscopic guidance. The guide wire and Obturator are removed, and the tip of the Guide is deflected by rotating the control knob on the handle to orient its position into the desired location for EndoAnchor implantation. EndoAnchors are loaded into the Heli-FX Applier from the EndoAnchor Cassette. The Heli-FX Applier is then advanced within the Heli-FX Guide until the distal end of the Applier is in contact with the endograft at the desired implant location. EndoAnchor implantation is accomplished in a two-stage process. Pressing the forward control button on the Applier control handle rotates the EndoAnchor in the forward direction. The EndoAnchor is rotated and partially driven out of the threaded housing. This is the initial implantation position or "pause position." At this point the physician can assess the placement of the EndoAnchor and decide whether to complete implantation or to remove the EndoAnchor and re-attempt placement. From the pause position, the EndoAnchor implantation process can be completed by pressing the forward button a second time or the EndoAnchor can be retracted by pressing the reverse button, which rotates the EndoAnchor back into the threaded housing. Audible tones and indicator lights during operation signal the position of the EndoAnchor and the available direction of motion. After implantation is completed, the Applier catheter is withdrawn and reloaded with another EndoAnchor from the Cassette. The Guide is repositioned to another location for EndoAnchor implantation. This process is repeated for each EndoAnchor to be implanted.

Figure 4 provides a fluoroscopic image demonstrating the implantation of EndoAnchors. It is recommended that a minimum number of EndoAnchors be placed based upon the native (healthy) aortic neck diameter, endograft type, and endograft angulation. Additional anchors may also be placed at physician discretion, or at the specific locations of Type I endoleaks to enhance sealing. Table 4 and Table 5 indicate the recommended minimum numbers of EndoAnchors based on if a bifurcated or tube endograft is used respectively.

The procedure is performed under general anaesthesia or local anaesthesia with sedation.

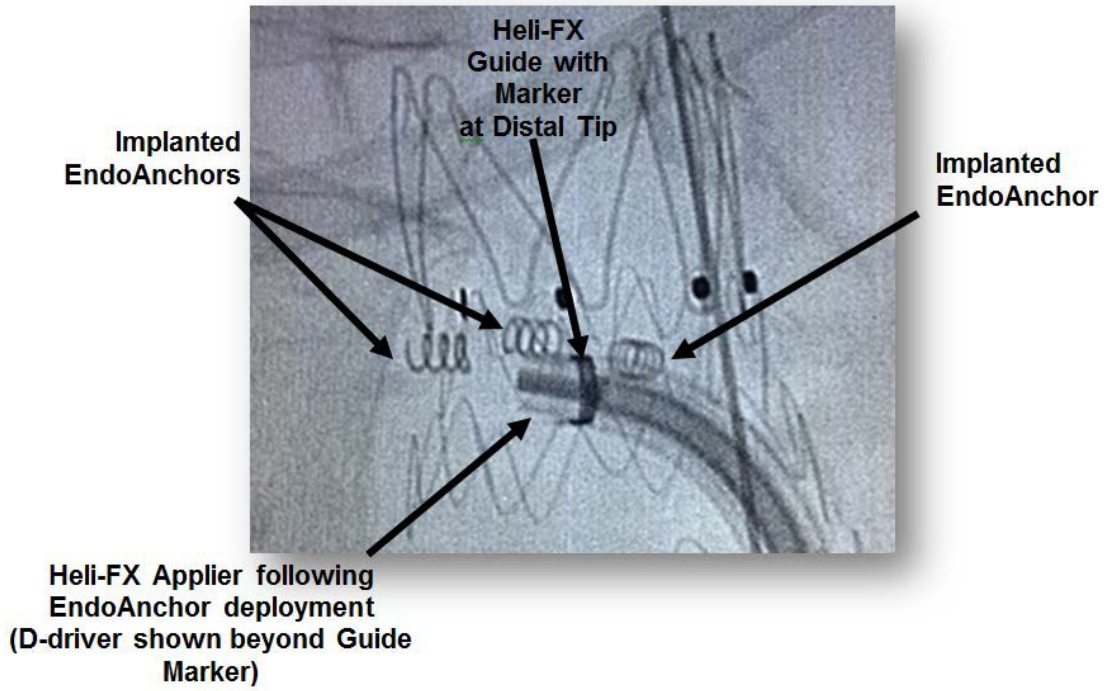

Figure 4 Fluoroscopic image of EndoAnchor implantation

Table 4 Recommended minimum number of EndoAnchors – bifurcated endografts

Aortic neck diameter (proximal)	Graft angulation ≤ 60˚
≤ 29 mm	4
30-32 mm	6

Table 5 Recommended minimum number of EndoAnchors – tube endografts

Aortic neck diameter (proximal or distal)	Graft angulation		
	≤ 60˚	>60-75 ˚	> 75-90 ˚
≤ 29 mm	4	4	4
30-32 mm	4	4	5
33-36 mm	4	5	7
37-40 mm	5	6	8
≥ 40 mm	5	7	9

Intended use

The Heli-FX EndoAnchor Systems are intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The Heli-FX Systems are indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion.

The EndoAnchor may be implanted at the time of the initial endograft placement, or during a secondary (i.e., repair) procedure.

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

No, the proposed medical service does not include a registered trademark.

29. 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?

As previously mentioned, the proposed service includes the transmural fixation of aortic endograft adjunct to EVAR/TEVAR using helical anchors. As such, the proposed service represents an adjunct to currently used treatments of patients with AAA/TAA. The success of EVAR/TEVAR relies on achieving an adequate proximal and distal seal to exclude the aneurysm from the systemic circulation. In a proportion of patients endoleaks will be observed intraoperatively or post-operatively. Endoleaks may compromise the aneurysm repair and is associated with a small risk of rupture. The addition of these helical anchors will improve the proximal seal between the endograft and the aortic wall and therefore reduce the risk of endoleaks or device migration.

30. 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):

There is no clear limitation on the provision of the proposed medical service. The proposed medical service will be delivered by vascular surgeons and the objective is for the service to be delivered once.

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

The healthcare resources utilisation of EVAR/TEVAR with adjunct helical anchors is the same as EVAR/TEVAR without helical anchors. CTA is required for pre-procedural planning (Chaikof et al 2018;

Robinson et al 2013). The procedure is performed using standard fluoroscopy under general anaesthesia or under local anaesthesia with sedation.

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

The proposed service will be performed by vascular surgeons

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

Not applicable

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

Not applicable

35. 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:

An independent Royal Australasian College of Surgeons (RACS) Board of Vascular Surgery was formed in 1997 to oversee vascular surgery training in Australasia. The independent RACS Board of Vascular Surgery would be an appropriate body to consult regarding training, qualification and accreditation requirements.

36. (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 is performed as an inpatient service either in the public or private hospital setting and requires an overnight stay in the hospital.

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

- ☒ Yes
- ☐ No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

38. 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):

Consistent with the clinical management algorithm for AAA/TAA as presented in Appendix A, the proposed comparators in the proposed patient populations are as follows:

Population 1	Prophylactic repair in patients at risk of endoleaks or stent migration with hostile neck anatomy	Comparator: Complex EVAR/TEVAR including fenestrated, branched or chimney grafts
Population 2	Therapeutic treatment to resolve Type IA endoleaks/device migration after EVAR/TEVAR.	Comparators: Revision EVAR/TEVAR (including addition of component pieces and/or repositioning of stent graft, and/or aggressive ballooning i.e. angioplasty) Open repair
Population 3	Therapeutic treatment to resolve late graft failure (Type IA endoleaks) after open repair	Comparator: EVAR/TEVAR Open repair

Based on historical MBS utilisation it is suggested that EVAR of an infrarenal AAA using a bifurcated stent is the most commonly performed procedure for the treatment of aortic aneurysms. As presented in Table 6, EVAR using the bifurcated or tube stent was accessed 867 times in 2017, whilst other procedures combined were used a total of 479 times in 2017, which includes all ruptured and unruptured treatments for TAA and AAA. There are no specific MBS item numbers for complex EVAR/TEVAR.

Table 6 MBS utilisation of procedures for the treatment of an AAA and TAA, 2017

Procedure description	**MBS item**	**2017**
Infrarenal abdominal aortic aneurysm – EVAR (tube)	33116	65
Infrarenal abdominal aortic aneurysm – EVAR (bifurcated)	33119	802
Infrarenal abdominal aortic aneurysm – open repair (tube)	33115	57
Infrarenal abdominal aortic aneurysm – open repair (bifurcated)	33118	56
Thoracic aneurysm repair	33103	45
Thoraco-abdominal aneurysm repair	33109	12
Suprarenal abdominal aortic aneurysm repair	33112	34
Thoracic ruptured aortic aneurysm repair	33145	6

Procedure description	MBS item	2017
Thoraco-abdominal ruptured aortic aneurysm	33148	1
Suprarenal abdominal ruptured aortic aneurysm	33151	5
Infrarenal abdominal aortic ruptured aneurysm (tube)	33154	15
Infrarenal abdominal aortic ruptured aneurysm (bifurcated)	33157	27

39. 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

The MBS items for the nominated comparators are provided in Table 7. Two item numbers are specific to EVAR (33116, 33119). There are no specific item numbers for complex EVAR. The MBS item descriptor for 33103 does not limit to endovascular or open repair of thoracic aneurysm (there are no items that specifically limited to TEVAR). There are several items for ruptured or unruptured open repair of aneurysms. Based on KOL feedback, there are multiple MBS item numbers relevant to the revision EVAR/TEVAR comparator procedures, including transluminal stents and balloon angioplasty insertion.

Table 7 Relevant MBS items for potential comparators

MBS item	MBS item descriptor	Fee
EVAR		
33116	INFRARENAL ABDOMINAL AORTIC ANEURYSM, replacement by tube graft using endovascular repair procedure, excluding associated radiological services	$1,399.00
33119	INFRARENAL ABDOMINAL AORTIC ANEURYSM, replacement by bifurcation graft to one or both iliac arteries using endovascular repair procedure, excluding associated radiological services	$1,5554.55
Open repair		
33103	THORACIC ANEURYSM, replacement by graft	$2,015.30
33109	THORACO-ABDOMINAL ANEURYSM, replacement by graft including re-implantation of arteries	$2,436.50
33112	SUPRARENAL ABDOMINAL AORTIC ANEURYSM, replacement by graft including re-implantation of arteries	$2,113.10
33115	INFRARENAL ABDOMINAL AORTIC ANEURYSM, replacement by tube graft, not being a service associated with a service to which item 33116 applies	$1,421.35
33118	INFRARENAL ABDOMINAL AORTIC ANEURYSM, replacement by bifurcation graft to iliac arteries (with or without excision of common	$1,579.30

	iliac aneurysms) not being a service associated with a service to which item 33119 applies	
33121	INFRARENAL ABDOMINAL AORTIC ANEURYSM, replacement by bifurcation graft to 1 or both femoral arteries (with or without excision or bypass of common iliac aneurysms) [a]	$1,737.25
Ruptured aneurysm		
33148	RUPTURED THORACO-ABDOMINAL AORTIC ANEURYSM, replacement by graft	$3,165.80
33151	RUPTURED SUPRARENAL ABDOMINAL AORTIC ANEURYSM, replacement by graft	$3,007.90
33154	RUPTURED INFRARENAL ABDOMINAL AORTIC ANEURYSM, replacement by tube graft	$2,225.90
33157	RUPTURED INFRARENAL ABDOMINAL AORTIC ANEURYSM, replacement by bifurcation graft to iliac arteries (with or without excision or bypass of common iliac aneurysms)	$2,481.50
33160	RUPTURED INFRARENAL ABDOMINAL AORTIC ANEURYSM, replacement by bifurcation graft to 1 or both femoral arteries	$2,481.50
Revision EVAR/TEVAR		
35300	TRANSLUMINAL BALLOON ANGIOPLASTY of 1 peripheral artery or vein of 1 limb, percutaneous or by open exposure	$515.35
35303	TRANSLUMINAL BALLOON ANGIOPLASTY of aortic arch branches, aortic visceral branches, or more than 1 peripheral artery or vein of 1 limb, percutaneous or by open exposure	$660.80
35306	TRANSLUMINAL STENT INSERTION, 1 or more stents, including associated balloon dilatation for 1 peripheral artery or vein of 1 limb, percutaneous or by open exposure	$609.90
35309	TRANSLUMINAL STENT INSERTION, 1 or more stents, including associated balloon dilatation for visceral arteries or veins, or more than 1 peripheral artery or vein of 1 limb, percutaneous or by open exposure	$762.35

[a] Negligible utilisation (MBS statistics)

40. 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):

The clinical algorithm provided in Appendix A shows the pathway after patients receive the proposed service in the prophylactic/acute setting. That is, the proposed service is also positioned in the therapeutic treatment to resolve Type IA endoleaks and late graft failures following EVAR/TEVAR and open repair.

Given the potential delayed complications with EVAR/TEVAR, lifelong surveillance usually once per year is indicated. This is usually performed using a combination of plain abdominal x-ray, duplex ultrasound and CTA (Robinson et al 2013). The same approach to surveillance will be used following EVAR/TEVAR with adjunct helical anchors.

Based on KOL feedback, as part of standard of care patients should be monitored 6 weeks post-operative scan. If at that time there is no evidence of endoleaks, then the patient should be monitored at 6 months, and at 12 months and annually from there on. In the case of small endoleaks at the 6 weeks post-operative follow-up, the patient would be monitored at 3 months, 6 months, 12 months and annually after that.

41. (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:

Fixation of the endograft using helical anchors is adjunct to EVAR/TEVAR. In the prophylactic/acute setting, it is expected that the proposed service will replace complex EVAR. The use of helical anchors adjunct to EVAR/TEVAR as therapeutic treatment to resolve Type IA endoleaks/device migration after EVAR/TEVAR or late graft failure after open repair, will replace revision EVAR/TEVAR or open repair. The proposed service is not expected to grow the market due to the current availability of standard EVAR, complex EVAR and open repair, as such 100% of utilisation is expected to be derived from substitution. The extent to which each of the comparators are expected to be substituted will be addressed in the submission-based assessment (refer to Part 7 for details).

42. 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 40 as baseline):

Compared with complex EVAR/TEVAR, it is expected that fixation of endograft with helical anchors will result in fewer re-hospitalisations as a result of lower re-intervention rate. The reintervention rate in the ANCHOR registry was 3.8% at 14 months in patients who had fixation with helical anchors. For reference, an Australian, multi-centre, retrospective study reports that 24.1% (14/58) of patients undergoing AAA repair using fenestrated endografts required secondary interventions. Ziegler et al (2007) reported that 24.7% of patients receiving fenestrated/branched EVAR required reintervention, with all reinterventions performed within the first 14 months. However, Verhoeven et al (2010) reported that 9% of patients with fenestrated stent grafting for short-necked and juxtarenal abdominal aortic aneurysm required re-intervention. This will be further explored in the submission-based assessment.

Compared with OR, a major difference in resource utilisation is shorter hospitalisation associated with the fixation of endograft with helical anchors due to the less invasive nature of the endovascular procedure. A retrospective, observational analysis of consecutive patients undergoing elective and emergency AAA repair, from 2009 until 2011, in a single New Zealand centre reported significantly shorter length of stay with EVAR compared with OR (4 versus 9 days; p vs OR 9 days). Furthermore, length of stay was longer for ruptured aneurysm compared with electively repaired aneurysm (Peek et al. 2016).

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

43. 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):

Across all patient populations, it is expected that the fixation of endograft with helical anchors adjunct to EVAR/TEVAR is at least non-inferior on effectiveness and safety compared with its comparators. It is expected that fixation of endograft with helical anchors will lower reintervention rates relative to complex EVAR/TEVAR.

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

☐ Superiority
☒ Non-inferiority

45. 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:

Device or procedure-related adverse events

Serious adverse events

Procedure-related mortality

Clinical Effectiveness Outcomes:

Freedom from type IA endoleak or graft migration

Rate of re-intervention

Rate of Type IA endoleaks and graft migration

Aneurysm sac expansion

Rupture

Aneurysm-related mortality

Conversion to open repair

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

Li (2013) presents a meta-analysis of AAA prevalence across general populations. This study included RCTs, cross-sectional and prospective cohort studies that reported data involving the prevalence of patients with AAA. The pooled prevalence of AAA was reported to be 4.8% (4.3%, 5.3%) across all 56 studies, and 6.7% (6.5%, 7.0%) across the 4 Australian studies included. Application of prevalence estimates from Li 2013 to the Australian population, results in an estimated AAA population of 1,716,533 in 2019 (25,619,895 * 6.7%). This does not reflect the true number of patients that will be diagnosed with an AAA/TAA and treated in a clinical setting. Diagnosis of AAA/TAAs is limited as they are often asymptomatic, detected through incidental finding from imaging or physical examination (Aggarwal 2011). Furthermore, among those AAA/TAAs diagnosed, small fusiform aneurysms are often left untreated ongoing, with ongoing monitoring provided to evaluate aneurysm growth.

In addition to diagnosis issues in asymptomatic patients and the watch and wait treatment approach to small fusiform aneurysms, helical anchoring is an adjunctive service that is not expected to grow the overall AAA/TAA treated population. Therefore, it is suggested that incidence of treatment is the most appropriate method of estimating the proposed population.

Based on MBS utilisation there were an estimated 1,125 procedures for the repair of aortic aneurysms repair in 2017, Table 8, assumed representative of prophylactic/acute repair (Population 1; Q25). Considering ABS population projections[1], the incidence of prophylactic/acute repair of AAA/TAAs is estimated to be 4.5 per 100,000 (1,125/24,781,121).

Table 8 MBS utilisation of procedures for the treatment of an AAA and TAA, 2017

Procedure description	MBS item	2017
Infrarenal abdominal aortic aneurysm – EVAR (tube)	33116	65
Infrarenal abdominal aortic aneurysm – EVAR (bifurcated)	33119	802
Infrarenal abdominal aortic aneurysm – open repair (tube)	33115	57
Infrarenal abdominal aortic aneurysm – open repair (bifurcated)	33118	56
Thoracic aneurysm repair	33103	45
Thoraco-abdominal aneurysm repair	33109	12
Suprarenal abdominal aortic aneurysm repair	33112	34
Thoracic ruptured aortic aneurysm repair	33145	6
Thoraco-abdominal ruptured aortic aneurysm	33148	1
Suprarenal abdominal ruptured aortic aneurysm	33151	5
Infrarenal abdominal aortic ruptured aneurysm (tube)	33154	15
Infrarenal abdominal aortic ruptured aneurysm (bifurcated)	33157	27
Total aortic aneurysm repair procedures	-	1,125

The number of revision treatments for AAA/TAAs associated with type IA endoleaks post EVAR and open repair (Population 2 and 3; Q25), is estimated via the application of endovascular reintervention rates from Giles (2012). Giles (2012) reports endovascular reintervention within the first 6 years after 9.2% (2,095/22,826) of prophylactic/acute EVAR procedures and 0.8% (180/22,826) of prophylactic/acute open repair procedures. Applying reintervention rates to procedure estimates in Table 8 results in an estimated revision population of 83 (9.2%*867+0.8%*258), equivalent to an incidence of 0.33 per 100,000 (82/24,781,121).

[1] http://stat.data.abs.gov.au/Index.aspx

[Note: Reintervention rates applied only account for those reinterventions treated endovascularly. Total reinterventions were reported in 29% of patients post EVAR and 26% of patients post open repair procedures.]

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

EVAR plus helical anchoring is intended as a once off procedure. It is acknowledged that a small proportion of patients will receive a secondary procedure (reintervention) due to endoleaks. Current evidence (Muhs 2017; ANCHOR registry) suggests that the addition of helical anchoring to EVAR results in a reintervention rate of approximately 3.8% at 14 months.

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

EVAR plus helical anchoring is intended as a once off procedure barring reintervention, see Q47.

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

Helical anchoring is an adjunctive therapy to be used in addition to EVAR procedures. As such, a market share approach is used to estimate the number of patients that will utilise helical anchoring in the first full year of MBS listing. Figure 5 presents the historical market size of aortic repair procedures on the MBS from 2007 to 2017 disaggregated into; infrarenal abdominal aneurysm repair, suprarenal abdominal aortic aneurysm repair, thoracic aneurysm repair, thoraco-abdominal aneurysm repair and ruptured aortic aneurysm repair.

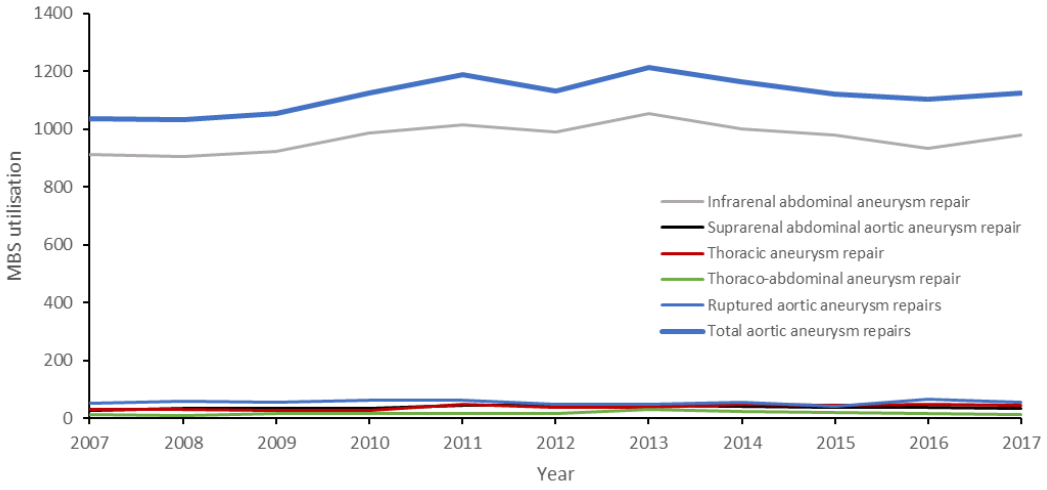

Figure 5 Historical MBS utilisation of EVAR and open repair in treating AAA/TAA

Note: EVAR includes MBS items: 33116 and 33119. Open repair includes MBS items: 33115 and 33118.

Figure 5 illustrates that utilisation of aortic aneurysm repair MBS items has remained relatively stable over the last decade. Based on historical utilisation it is assumed that utilisation of aortic aneurysm repair MBS items will linearly increase from 2017 in line with Australian population growth based on ABS projections[2]. In line with KoL advice, presented in Q26, it is assumed that 20% of patients have hostile neck anatomy, and 95% of patients will be suitable for endovascular repair. Uptake of helical anchoring among these patients (Population 1) is estimated to be 50% in the first full year of listing. High initial uptake is estimated based on the assumption of reduced reintervention rates relative to complex EVAR, as presented in Q42 (3.8% for helical anchoring adjunct to EVAR vs 9-24% for fenestrated EVAR). The validity of this assumption will be explored in the submission-based assessment. In the first full year of listing it is estimated that helical anchoring will be used in 110 EVAR procedures for the prophylactic/acute repair of aortic aneurysms, Table 9.

[2] http://stat.data.abs.gov.au/Index.aspx

The utilisation of helical anchoring in revision settings (Populations 2 and 3) is estimated through the application of reintervention rates from Giles (2012) to prophylactic/acute repair estimates, outlined in Q46. As in the prophylactic/acute repair population, uptake is assumed to be 50% in the first year of listing. Based on these assumptions it is estimated that helical anchoring will be used in 42 revision EVAR procedures in the first year of listing, Table 9.

Across all populations it is estimated that 153 EVAR procedures will be performed with adjunct helical anchoring in the first full year of listing.

Table 9 Estimated utilsiation of EVAR with adjunct helical anchoring for the first full year of listing

Row	Parameter	Year 1 (2019)	Source
	Population 1: Prophylactic/acute repair		
A	Total AAA/TAA repair procedures	1,163	Calculated[a]
B	Prop. with hostile neck anatomy	[redacted]%	KoL advice
C	Total with hostile neck anatomy	233	A*B
D	Prop. suitable for endovascular repair	[redacted]%	KoL advice
E	Total suitable for endovascular repair	221	C*D
F	Uptake of EVAR with helical anchoring	[redacted]%	Assumption
G	Total EVAR procedures with helical anchoring	110	E*F
	Populations 2 and 3: Revision repair		
H	Estimated EVAR procedures	896	Calculated[a]
I	Prop. with type IA endoleak	9.2%	Giles 2012
J	Estimated revision procedures post EVAR	82	H*I
K	Estimated open repair procedures	267	Calculated[a]
L	Prop. with type IA endoleak	0.8%	Giles 2012
M	Estimated revision procedures post open repair	2	K*L
N	Total endovascular revision procedures	84	J+M
O	Uptake of helical anchoring	50%	Assumption
P	Total EVAR procedures with helical anchoring	42	N*P
	All populations		
Q	Total EVAR procedures with helical anchoring	153[b]	G+P

[a] MBS utilisation in 2017 (Table 8) * projected increase in Australian pop. between 2019 and 2017. EVAR procedures are assumed to include MBS items 33116 and 33119, whilst remaining are attributed to open repair.

[b]Result is subject to rounding error

50. 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:

Applying the same assumptions as presented in Q49, and linearly increasing uptake (5% per annum), it is estimated that 171 EVAR procedures with helical anchoring will be performed in the second year of listing, increasing to 208 in the fourth full year of listing (Table 10).

Table 10 Estimated utilsiation of EVAR with adjunct helical anchoring over years 2 to 4 of listing

Row	Parameter	Year 2	Year 3	Year 4	Source
	Population 1: Prophylactic/acute repair				
A	Total AAA/TAA repair procedures	1,182	1,201	1,220	Calculated[a]
B	Prop. with hostile neck anatomy	[redacted]%	[redacted]%	[redacted] %	KoL advice
C	Total with hostile neck anatomy	236	240	244	A*B
D	Prop. suitable for endovascular repair	[redacted] %	[redacted] %	[redacted] %	KoL advice
E	Total suitable for endovascular repair	225	228	232	C*D
F	Uptake of EVAR with helical anchoring	[redacted] %	[redacted] %	[redacted] %	Assumption
G	Total EVAR procedures with helical anchoring	124	137	151	E*F
	Populations 2 and 3: Revision repair				
H	Estimated EVAR procedures	911	925	940	Calculated[a]
I	Prop. with type IA endoleak	9.2%	9.2%	9.2%	Giles 2012
J	Estimated revision procedures post EVAR	84	85	86	H*I
K	Estimated open repair procedures	271	275	280	Calculated[a]
L	Prop. with type IA endoleak	0.8%	0.8%	0.8%	Giles 2012
M	Estimated revision procedures post open repair	2	2	2	K*L
N	Total endovascular revision procedures	86	87	88	J+M
O	Uptake of helical anchoring	[redacted] %	[redacted] %	[redacted] %	Assumption
P	Total EVAR procedures with helical anchoring	47	52	58	N*P
	All populations				
Q	Total EVAR procedures with helical anchoring	171	189	208	G+P

[a] MBS utilisation in 2017 (Table 8) * projected increase in Australian pop. between 2019 and 2017. EVAR procedures are assumed to include MBS items 33116 and 33119, whilst remaining are attributed to open repair.

NB. Result is subject to rounding error

PART 8 – COST INFORMATION

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

The insertion of helical anchors adjunct to EVAR is estimated to cost $XXX in treating AAA, and $[redacted] in treating TAA. Procedure costs include; EndoAnchor prostheses and consumables, stent graft prosthesis, stent graft insertion, anaesthesia (initiation and time units), imaging (CTA and fluoroscopy) and specialist attendance (surgeon, anaesthetist and nurse). The presented costing assumes the use of a bifurcated stent graft in AAA and a ≥180mm tube graft in TAA, and no adjunct transluminal stent insertion or balloon angioplasty. It is also assumed that 100% of patients are under general anaesthesia during the procedure. Table 11 provides a breakdown of included costs and associated sources.

Table 11 Procedure costs assoiated with the provision of EVAR and the adjunct insertion of helical anchors

	Cost	Source/calculation
AAA		
Endovascular graft insertion	$1,554.55	MBS item 33119 (bifurcated graft)
Stent graft	$11,909	PLAC [bifurcated graft (body and 2 limbs)]
EndoAnchor system[a]	$Confidential	Applicant
Anaesthesia[b]	$594.00	MBS item 20560 ($396) and 23101 ($198)
Fluoroscopy	$43.40	MBS item 60500
CTA (pre-procedural planning)	$510.00	MBS item 57350 (prophylactic) / 57351 (acute)
Total procedure cost	$[redacted]	Calculated
TAA		
Graft insertion[c]	$2,015.30	MBS item 33103
Stent graft	$13,920	PLAC [tube graft (≥180mm length)]
EndoAnchor pack[a]	$[redacted]	Applicant
Anaesthesia[b]	$594.00	MBS item 20560 ($396) and 23101 ($198)
Fluoroscopy	$43.40	MBS item 60500
CTA (pre-procedural planning)	$510.00	MBS item 57350 (prophylactic) / 57351 (acute)
Total procedure cost	$[redacted]	Calculated

[a] EndoAnchor deployment system includes a cassette of 10 EndoAnchors, an applicator and a steerable sheath.
[b] Assumed that all patients receive general anaesthesia. MSAC item 20560: Initiation of management of anaesthesia for open procedures on the heart, pericardium or great vessels of the chest; or percutaneous insertion of a valvular prosthesis. MSAC item 23101: 2:11 hours to 2:20 hours anaesthesia time units.
[c] MBS items for treatment of TAA are not classified into EVAR and open repair as is the case in AAA.

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

Across 319 patients included in the ANCHOR registry the estimated procedure duration for the provision of EndoAnchors in addition to EVAR was 138 minutes (SD: 76) (Jordan 2014). Jordan (2014) reports that on average the deployment of EndoAnchors accounted for 19 minutes (SD:17) of the total procedure time.

Patients in the primary treatment subgroup experienced a mean procedure duration was 138 minutes (SD: 71), including 18 minutes (SD: 21) for EndoAnchor implantation. Patients in the revision subgroup experienced similar procedure durations, 143 minutes (SD: 89), including 21 minutes (SD: 22) for EndoAnchor implantation. As such, it is expected that the insertion of helical anchors in association with EVAR will take approximately 140 minutes whether performed as primary care or as a revision service.

Table 12 Procedure durations across 319 patients included in the ANCHOR registry, Jordan (2014)

Parameter	Primary	Revision	All
N	242	77	319
Procedure duration, min (SD)	138 (71)	143 (89)	138 (76)
EndoAnchor implantation duration, min (SD)	18 (21)	21 (22)	19 (21)

53. 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.

Category 3 – THERAPEUTIC PROCEDURES
Proposed item descriptor: ABDOMINAL OR THORACIC AORTIC ANEURYSM, transmural fixation of endograft to the aorta adjunct to endovascular aneurysm repair using helical anchors. Fee: $TBC

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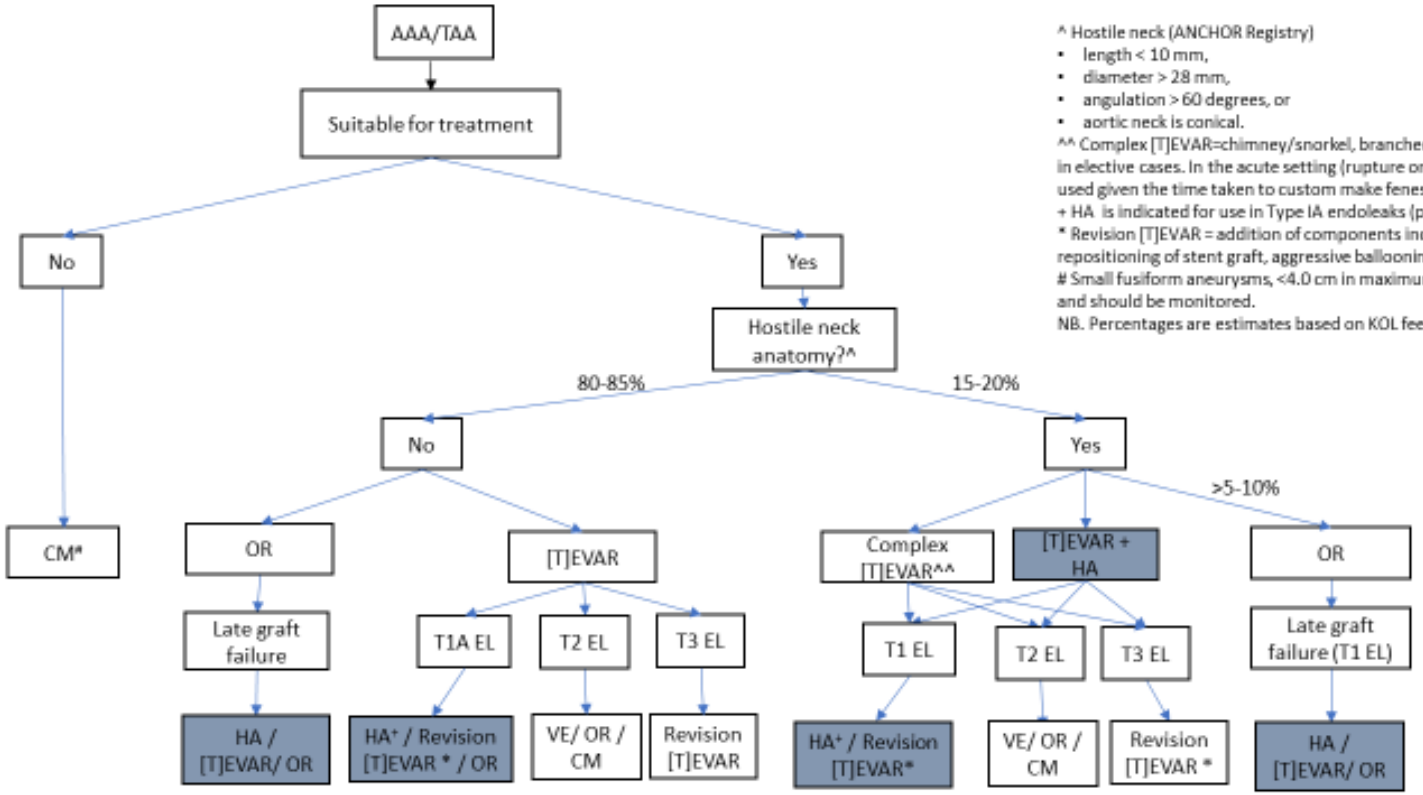
Appendix A Clinical algorithm for the management of AAA/TAA



^ Hostile neck (ANCHOR Registry)
- length < 10 mm,
- diameter > 28 mm,
- angulation > 60 degrees, or
- aortic neck is conical.

^^ Complex [T]EVAR=chimney/snorkel, branched, fenestrated. Mostly fenestrated used in elective cases. In the acute setting (rupture or symptoms) chimney is predominantly used given the time taken to custom make fenestrated grafts
+ HA is indicated for use in Type IA endoleaks (proximal)
* Revision [T]EVAR = addition of components including cuffs, extenders or converters, repositioning of stent graft, aggressive ballooning (angioplasty)
# Small fusiform aneurysms, <4.0 cm in maximum diameter, are at low risk of rupture and should be monitored.
NB. Percentages are estimates based on KOL feedback and refer to elective cases

AAA=abdominal aortic aneurysm; CM=conservative management; OR=open repair; T1 EL=type I endoleak, T2 E:L=type II endoleak, T3 EL=Type III endoleak; HA=helical anchors adjunct to EVAR/TEVAR; EVAR=endovascular aneurysm repair; TAA=thoracic aortic aneurysm; TEVAR=thoracic endovascular aortic repair; OR=open repair; VE= Vessel embolisation .

PART 9 – FEEDBACK

The Department is interested in your feedback.

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

Insert approximate duration here

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

☐ Yes
☐ No

(b) If no, provide areas of concern:

Describe areas of concern here

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

☐ Yes
☐ No

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

Insert feedback here

57. (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?

☐ Yes
☐ No

(b) If yes, please advise:

Insert feedback here