Australian Government

Department of Health

Application 1553:

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

Ratified PICO Confirmation

(To guide a new application to MSAC)

(Version 1.0)

Summary of PICO/PPICO criteria to define the question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Component	Description
Patients	Population 1: • Patients with an aortic abdominal aneurysm or thoracic aortic aneurysm who are undergoing initial EVAR/TEVAR and who have a hostile neck anatomy (defined in the application as length <10mm, diameter >28 mm, angulation >60 degrees or aortic neck is conical for EVAR and diameter ≥ 40mm, length <20 mm for TEVAR). Population 2: • Patients with a Type IA endoleak and/or graft migration during or after EVAR/TEVAR aneurysm repair • Note graft migration defined as movement of the endograft greater than 10 mm; or, any migration of the graft which necessitates any intervention or causes endoleaks.
Intervention	Population 1: • Helical anchor used adjunctively to EVAR/TEVAR Population 2: • Revision/repair using T/EVAR standard of care and helical anchors
Comparator	Comparator for Population 1: • Initial EVAR/TEVAR with complex grafts (fenestrated, branched or chimney grafts) Comparator for Population 2: • Revision EVAR/TEVAR including the addition of component pieces and/or repositioning of the stent graft, and/or aggressive ballooning, i.e. angioplasty) • Open repair
Outcomes	*Patient relevant* Safety • Device or procedure related adverse events • Serious adverse events • Procedure-related mortality Effectiveness • Freedom from Type IA endoleak or graft migration • Sac regression • Rate of reintervention • Rate of Type IA endoleak and graft migration • Rupture • Aneurysm-related mortality • Conversion to open repair • Quality of life *Healthcare system* • The following outcomes are proposed as being relevant to the Healthcare system • Costs associated with the intervention and comparators including costs of the helical anchors, costs of stents, anaesthesia, pre-, peri- and post-procedure imaging, time to perform intervention and comparator techniques and all other costs • Length of hospital stay and use of hospital resources • Follow-up requirements (including ongoing imaging) • Training costs where borne by the healthcare system

PICO or PPICO rationale for therapeutic and investigative medical services only

Population

This PICO Confirmation proposes use of helical anchors in two populations:

1. Patients with an aortic abdominal aneurysm or thoracic aortic aneurysm who are undergoing initial EVAR/TEVAR and who have a hostile neck anatomy (defined in the application as length <10mm, diameter >28 mm, angulation >60 degrees or aortic neck is conical for EVAR and diameter ≥ 40mm, length <20 mm for TEVAR).

2. Patients with a Type IA endoleak and/or graft migration during or after EVAR/TEVAR aneurysm repair, where migration is defined as movement of the endograft greater than 10 mm; or, any migration of the graft which necessitates any intervention or causes endoleaks.

Background

An aneurysm is a localised dilation of an artery; where the diameter is 1.5 times greater than usual. The abdominal aorta is generally considered to have an aneurysm when its diameter exceeds 30 mm; for the thoracic aorta aneurysm (TAA) is defined as diameters greater than 40 mm.[1] Aortic aneurysms are commonly identified incidentally and are usually asymptomatic. Routine screening for aortic aneurysms is currently not conducted in Australia.[2, 3]

Rates of abdominal aortic aneurysm (AAA) increase with age; AAA is rare in patients less than 50 years yet affects four to seven per cent of men and one to two per cent of women aged over 65 years.[3] Other risk factors for AAA include smoking, family history, atherosclerosis, hypertension, hypercholesterolemia and other vascular aneurysms.[3] Additional risk factors for TAA include autoimmune, inflammatory and connective tissue disorders and chest trauma.[4] AAA is the most common type of aortic aneurysm, with a total of 3,867 cases recorded in Australia in the 2016/17 financial year; of which 549 aneurysms were ruptured.[5] A total of 1,126 cases of TAA were recorded in Australia during 2016/17 of which 48 were ruptured.[6] Approximately 1,000 deaths per year are attributed to aortic aneurysm.[3]

The natural history of both AAA and TAA is progressive dilation; with larger aneurysms dilating more rapidly.[4, 7] With increasing size there is a corresponding risk of rupture which is associated with approximately 80 per cent mortality.[1] Treatment recommendations for AAA and TAA are based on balancing risk of treatment with risk of rupture. Generally AAA is recommended for repair when: larger than 5.5 cm in diameter for men; larger than 5 cm for women; an aneurysm is rapidly growing (>1 cm per year); or, when an aneurysm is symptomatic (abdominal/back pain, distal embolism).[3, 8] Outside these criteria it is recommended that patients undergo regular surveillance at intervals determined by the size of the AAA. Risk of rupture and suggest surveillance timeframes are outlined in Table 1. TAA are recommended for repair when their diameter exceeds 6 cm due to the significantly increased risk of rupture.[8]

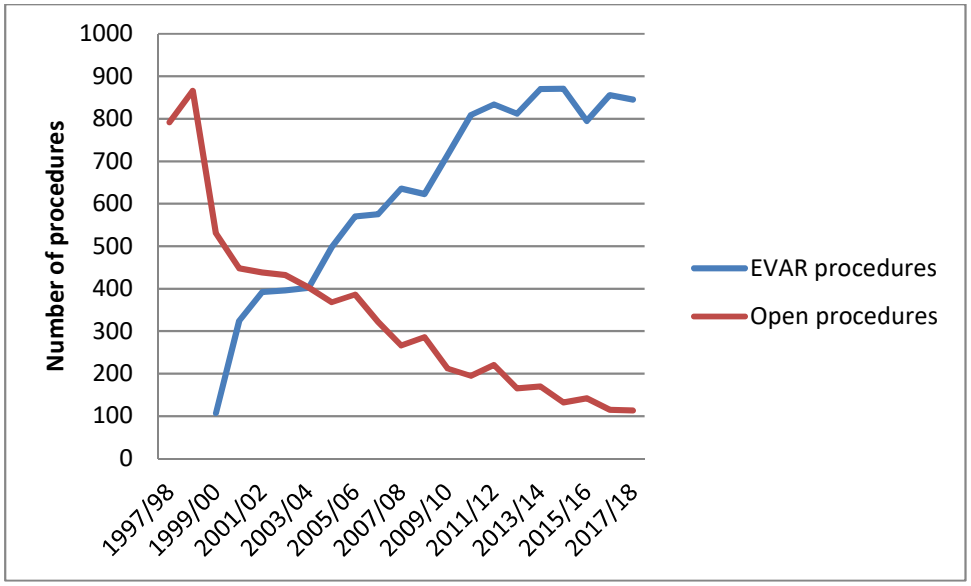
Table 1 12-month risk of AAA rupture by size[3, 9]

AAA diameter (cm)	Risk of rupture (%/year)	Suggested surveillance intervals
3.0-3.9	0	24 months
4.0-4.9	1	6-12 months
5.0-5.9	1-10	3 months
6.0-6.9	10-22	NR
>7.0	30-50	NR

Source: adapted from Robinson et al. (2013)[3] and Aggarwal et al. (2011)[9]. Note aneurysms >5.5 cm in diameter are indicated for treatment.
Abbreviations: AAA = abdominal aortic aneurysm

Surgical repair of AAA and TAA can be performed using open or endovascular procedures; with endovascular method becoming increasingly favoured in Australia over the last 20 years (Figure 1).[3]. Data from the Australasian Vascular Audit between 2010 and 2014 shows that 65 per cent of AAA repairs and 93 per cent of TAA repairs were endovascular (including repairs for ruptured aneurysms).[10] Expert feedback is that there are regional differences in the proportion of repairs carried out endovascularly; however, for example in Sydney, up to date figures estimate that 90 per cent of procedures for aneurysm repair are endovascular.[11] The current application is concerned with the use of helical anchors in conjunction with endovascular aneurysm repair (EVAR) and thoracic endovascular aneurysm repair (TEVAR) procedures.

Figure 1 MBS claims for open and endovascular AAA repair procedures[8]



Source: MBS Item Statistics data[12] and adapted from Robinson et al. (2013)[3]
Abbreviations: MBS = Medicare Benefits Schedule, EVAR = endovascular aneurysm repair

The Application documents for this PICO contain a detailed description of aneurysm repairs.[13] Briefly, EVAR involves feeding the stent-graft system through the femoral arteries to the correct position in the aorta using guidewires and catheters.[14] Open repair involves implantation and suturing of a synthetic graft to replace the diseased portion of the aorta.[14] Endovascular procedures are less invasive and are associated with lower mortality than open aneurysm repair (Table 2).[3, 9] EVAR/TEVAR are however associated with increased rates of postoperative complications requiring reintervention; namely endoleaks. Patients with hostile neck anatomy may be particularly prone to

these.[15, 16] Patients predisposed to, or suffering from, Type IA endoleaks make up the target populations of this application.

Table 2 Comparative mortality associated with EVAR and open aneurysm repair of AAA.[3]

Trial	EVAR mortality (%)	Open repair mortality
EVAR1	2.3	6.0
DREAM	1.2	4.6
OVER	0.5	3.0

Source: Adapted from Robinson et al. (2013)[3]
Abbreviations: EVAR = endovascular aneurysm repair, DREAM = Dutch Randomized Endovascular Aneurysm Management, OVER = Open versus Endovascular Repair Trial

Population 1

> *Patients with an aortic abdominal aneurysm or thoracic aortic aneurysm who are undergoing initial EVAR/TEVAR and who have a hostile neck anatomy (defined in the application as length <10mm, diameter >28 mm, angulation >60 degrees or aortic neck is conical for EVAR and diameter ≥ 40mm, length <20 mm for TEVAR).*

A hostile neck anatomy for patients undergoing EVAR is defined on page 14 of the Application as:

- length <10mm, diameter >28 mm, angulation >60 degrees or aortic neck is conical (EVAR)[13]

No definition for hostile neck anatomy for a TEVAR procedure is explicitly provided in the application; however, the Applicant describes on page 19 of the Application states "proximal and distal landing zones should have a diameter <40 mm and length ≥ 20 mm) for TEVAR.[13]

Anatomic characteristics determine the degree of difficulty in performing EVAR and are expected to influence rates of: technical success; endoleak; migration; conversion to open repair; and, need for secondary procedures.[17] Patients with hostile neck anatomy are at heightened risk of Type I endoleak, reintervention and aneurysm related-mortality.[18] Expert advice is that all patients with a diagnosed AAA or TAA who are indicated for surgery will undergo CT angiography (CTA) as part of the surgical planning process. Expert advice is that the results from the CTA are also used to determine if the patient has hostile neck anatomy. [11]

It has been reported in the literature that approximately 20 per cent of patients have a neck anatomy which is unsuitable for standard stent graft implantation.[19] Expert advice is that up to 30 per cent of patients with AAA or TAA in Australia may meet the definition of "hostile neck" as defined above.[11] AIHW data for 2016/17 indicates that there were 3,318 cases of non-ruptured AAA in Australia and 1,078 cases of non-ruptured TAA. Based on these figures the total number of patients who may be diagnosed with an aneurysm and have a hostile neck anatomy annually is 664 to 995 for AAA and 216 to 323 for TAA. Noting; however, that not all patients diagnosed with an aneurysm require surgery.

MBS item utilisations for aneurysm repair procedures in the 2017/18 financial year are presented in Table 3.

Table 3 MBS utilisation for aneurysm repair

	MBS item	Description	2017/18 claims
AAA repair	33116	Intrarenal AAA – EVAR (tube)	54
	33119	Intrarenal AAA – EVAR (bifurcated)	791
	33115	Intrarenal AAA – open repair (tube)	53
	33118	Intrarenal AAA – open repair (bifurcated)	60
	33112	Suprarenal AAA repair	26
	33121	Intrarenal AAA (bifurcation graft to 1 or both femoral arteries)	8
TAA repair	33103	TAA repair	32
Total			1024

Note: MBS item descriptors do not specify if suprarenal abdominal or thoracic procedures are endovascular or open.
Source: Medicare Item Statistics data [12]

Based on these figures; in 2017/18 there were potentially 205 to 307 patients who would comprise Population 1 annually based on a rate of hostile anatomy of 20 to 30 per cent.

Rationale for Population 1

PASC confirmed the proposed definition for hostile neck anatomy was appropriate.

Population 2

> *Patients with a Type IA endoleak and/or graft migration during or after EVAR/TEVAR aneurysm repair*

Type 1A endoleak

Endoleaks are an acknowledged complication arising from EVAR/TEVAR which can be identified immediately following the procedure or at any time in the future.[20] There are five types of endoleaks as described in the 2014 ESC Guidelines on the diagnosis and treatment of aortic diseases (Table 4).[21]

Table 4 Types of endoleak [21]

Type of endoleak	Description
Type I	Leak at graft attachment site above, below, or between graft components (Ia: proximal attachment site; Ib: distal attachment site).
Type II	Aneurysm sac filling retrogradely via single (IIa) or multiple branch vessels (IIb)
Type III	Leak through mechanical defect in graft, mechanical failure of the stent-graft by junctional separation of the modular components (IIIa), or fractures or holes in the endograft (IIIb)
Type IV	Leak through graft fabric as a result of graft porosity
Type V	Continued expansion of aneurysm sac without demonstrable leak on imaging (endotension, controversial)

Source: adapted from Erbel et al. (2014)[21]

EndoAnchor is proposed as a treatment for Type IA endoleaks only.[13] Type IA endoleaks occur when there is an incomplete seal at the graft attachment site and may develop immediately following placement of the graft or postoperatively.[20, 21] Expert advice is that endoleaks which develop perioperatively will be detected by routine angiography performed at the conclusion of every TEVAR and EVAR procedure.[11] Type IA endoleaks developing post-surgery will be detected during follow-up imaging which is recommended for every patient who undergoes and EVAR or TEVAR procedure.[20, 21] The Department of Health, Western Australia recommends an initial CTA and colour duplex

ultrasound (US) for all patients undergoing endovascular aneurysm repair at one month and then 12 months postoperatively followed by ongoing annual surveillance with colour duplex US and five-yearly CTA or non-contrast CT.[22] If left undetected and therefore untreated, Type IA endoleaks may eventually rupture; therefore it is recommended to treat Type IA endoleaks as they are detected.[20]

Data from the Australasian Vascular Audit from 2010 to 2014 shows that Type I endoleak was observed following 148 out of 6,616 elective (non-ruptured) EVAR procedures (2.23%) and 17 out of 509 TEVAR procedures (3.34%).[10] Note; the audit data does not break down leaks into Type IA and Type IB. The rates of Type I endoleak reported in the Audit are lower than rates provided by the Applicant (Table 9, page 33 of the Application).[13] The Applicant has reported a Type IA endoleak rate of 9.1% from Jordan et al (2014).[23] Rates of Type I endoleak reported in the EVAR 1 trial were 5.48 per cent at 4 year follow-up.[24] Harris et al. (2000) reported a total Type I endoleak rate of 8.6 per cent (201/2325) at a mean of 12 months follow-up. Further, the ratio of Type IA to Type IB endoleak was approximately 1:2.[25] Assuming the true rate of Type IA endoleak post-EVAR/TEVAR is between one and three per cent then Population 2 is expected to contain 9 to 30 patients annually based on 2017/18 financial year MBS claims (Table 3).[12]

Graft migration

Graft migration has been defined by the Applicant as:

- Movement of the endograft greater than 10 mm; or,
- any migration of the graft which necessitates any intervention or causes endoleaks.

The Society for Vascular Surgery/American Association for Vascular Surgery reporting standards for endovascular aortic aneurysm repair define endograft migration as “movement greater than 10 mm relative to anatomic landmarks or any migration leading to symptoms or requiring therapy”.[26]

Even in the absence of endoleak, device migration may lead to adverse outcomes for patients including kinking, limb thrombosis and eventually ischemia.[27, 28] Device migration is more common following EVAR with rates ranging from 1 to 45 per cent depending on the type of stent graft used; [27-29] For TEVAR migration rates are reportedly between one and three per cent.[30] Migration typically occurs two years or more following implantation. The primary causes of migration are aneurysm neck dilation, inadequate stent graft fixation or hostile neck anatomy[20, 27] Not all migrations require treatment; treatment may be required when the patients is experiencing symptoms or with loss of proximal fixation length (according to manufacturer’s recommendations for the stent graft).[28]Rationale for Population 2

Use of helical anchors in patients who have experienced aneurysm rupture is outside the scope of the Application.

The Applicant’s clinical expert suggested that patients who have Type IB, Type III or Type V endoleaks may benefit from helical anchor use; however, the current application is limited to patients with a Type IA endoleak [31]. Alternatively, clinical expertise is that helical anchors may be useful in patients who have undergone TAA repair and have a Type IB endoleak.[11] PASC confirmed these indications were not part of the current Application.

Intervention

The proposed intervention for Population 1 is a helical anchor used adjunctive to EVAR/TEVAR. The proposed intervention for Population 2 is revision/repair using EVAR/TEVAR standard of care and helical anchors.

The Heli-FX™ Endoancor™ system (Medtronic Inc. MN, USA) is the only anchor for use in preventing or repairing endoleaks which is listed on the ARTG. The ARTG listings for helical anchors are provided in Table 5.

Table 5 ARTG listings for helical anchor systems [13, 32]

Product, ARTG number, Sponsor, Class	Product description	Intended purpose
Aptus Heli-FX EndoAnchor System 283911 Medtronic Australasia Pty Ltd Medical Device Included Class III	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
Aptus Heli-FX Thoracic EndoAnchor System 283912 Medtronic Australasia Pty Ltd Medical Device Included Class III	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. It 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.
Aptus Heli-FX EndoAnchor System 298952 Medtronic Australasia Pty Ltd Medical Device Included Class III	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. It 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
Heli-FX Thoracic Endoanchor System 298953 Medtronic Australasia Pty Ltd Medical Device Included Class III	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. It 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.

Source: Adapted from the Application documents (page 6)[13] and Australian Register of Therapeutic Goods[32]
Note: Items with numbers 259875 and 259832 are also listed on the ARTG as Heli-FX EndoAnchor systems for export only.
Abbreviations: ARTG = Australian Register of Therapeutic Goods

Helical anchors are implanted during either an initial EVAR/TEVAR to prevent endoleak (patients with hostile anatomy), repair an endoleak detecting immediately following graft placement or during EVAR/TEVAR undertaken to repair a postoperatively detected endoleak. For patients with hostile anatomy the Applicant states that helical anchors are used in conjunction with "standard" EVAR grafts. These are defined as tube and bifurcated grafts in the Application (page 19).[13] This intended usage was supported by clinical expertise provided to the Assessment group.[11] The helical anchor is purported to improve the seal between the graft and the vessel, fixing the graft into the correct position.[13]

Note: The following information was sourced from the Application documents (pages 22-24) and is specific to the Heli-FX EndoAnchor (EndoAnchor) system.[13]

- The EndoAnchor is a metal-alloy helical shaped device that is stapled through the graft into the aortic wall. Each anchor is 4.5 mm in length and 3 mm in diameter and is supplied in a cassette of 10 anchors. Additionally, the EndoAnchor system also includes the Heli-FX Applier for implementation and the Heli-FX guide, a steerable guide sheath, for access and delivery. Separate variants are available specific to either abdominal or thoracic aneurysm repair procedures.
- Implantation is through the same vascular access as for EVAR/TEVAR procedures and is performed under fluoroscopic guidance. Implantation is performed by the vascular surgeon performing the EVAR/TEVAR procedure. A detailed description of the implantation process is provided on page 23 of the Application documents. The same implantation procedure is used regardless of the variant of anchor used, type of graft being anchored and whether the procedure is to prevent or repair an endoleak.
- Implantation of EndoAnchor is performed under general anaesthetic or local anaesthesia with sedation. Advice from a vascular surgeon is that choice of anaesthesia is determined for the EVAR/TEVAR procedure being performed and that implantation of an EndoAnchor does not affect the type of anaesthetic required.[13] EVAR/TEVAR are performed as in-patient services in both the private and public health settings and require an overnight stay.[31]

The EndoAnchor manufacturer's instructions for use note that:

- *"The EndoAnchor, Heli-FX EndoAnchor system, and Heli-FX Thoracic EndoAnchor system have been evaluated via in vitro testing and determined to be compatible with the Cook Zenith™*, Cook Zenith TX2™*, Gore Excluder™*, Gore TAG™, Medtronic AneuRx™, Medtronic Endurant™, Medtronic Talent™ AAA, Medtronic Talent™ TAA, and Medtronic Valiant™"*[33]
- Expert advice is that these grafts make up approximate 95 per cent of grafts used in Australia at this time.[11, 31]

The Applicant has provided a guide as to the minimum number of EndoAnchors required to be implanted based on a patients' anatomy and graft type (reproduced in Table 6 and Table 7). Additional anchors can be implanted at the surgeon's discretion.

Table 6 Recommended minimum number of EndoAnchors required – bifurcated grafts

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

Source: Application documents pages 23-24[13]

Table 7 Recommended minimum number of EndoAnchors required – tube grafts

		Graft angulation	
Aortic neck diameter (proximal or distal)	**≤ 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

Source: Application documents page 24[13]

Expert advice is that no additional imaging is required for EndoAnchor use in addition to that required for EVAR/TEVAR. Prior to the aneurysm repair procedure CTA is performed to assess the anatomy of the aorta, this is used to determine whether a patient has a hostile neck anatomy and what type of graft will be required.[13] Follow-up imaging is performed as required for EVAR/TEVAR procedures (discussed in Population section above).[22]

Should a Type IA endoleak be discovered post-EndoAnchor implantation, expert advice is that additional EndoAnchors can be implanted to stop the leak. If this procedure is unsuccessful and the Type IA endoleak persists, other techniques (graft extension, cuffs) would then be used.[11]

EndoAnchors are reported to be widely used across all Australian States and Territories in both the public and Private health systems.[11] Currently, if EndoAnchors are used the cost of the device is borne either by the hospital, the patient's insurer (if they agree to cover this cost), or by the patient themselves.[11]

Rationale

In Australia, EndoAnchors are only available in a 10-anchor cassette. Internationally, a 5-anchor cassette is also available. This may have cost implications should fewer than five or more than ten anchors be required for a patient.

Comparator

Comparator for Population 1

The proposed comparator for Population 1 is use of complex grafts (defined in the Application documents as fenestrated, branched or chimney grafts, pages 19 and 26). [13]

In patients with hostile anatomy there may be insufficient healthy aorta above the graft to provide adequate sealing; therefore standard (tube and bifurcated) grafts may not be appropriate for use.[19] In this patients group the current standard of care in Australia is repair with EVAR/TEVAR using complex grafts.[11]

Complex grafts can be fenestrated, branched or chimney grafts.

Fenestrated grafts are composite devices with a customisable proximal body and off-the-shelf bifurcated distal body. The customisable portion of the grafts typically contains one to four fenestrations which preserve blood flow to the renal and super mesenteric arteries and the celiac axis. These fenestrations allow the graft to be positioned higher than a standard graft to improve sealing and reduce the occurrence of Type IA endoleaks.[34, 35] Grafts are manufactured based on individual patient anatomy as determined by pre-surgical CTA.[11] Fenestrated grafts are reportedly not recommended for patients with ruptured aneurysm (noting this indication is outside the scope of the Application).[13]

Branched grafts are similar to fenestrated grafts in that they are used when visceral vessels are located in the target sealing zone of the graft.[35] The grafts are customisable for an individual patient's anatomy; with branches extending into the adjacent vessels; thereby allowing improved sealing over standard grafts [35, 36]

Due to their customisable nature; fenestrated and branched grafts can be expensive and may be subject to long wait times (1-2 months) for manufacture.[37]

Chimney grafts involve the insertion of additional stents into aortic side-branches; with the proximal end of these stents extending into the aorta parallel to the graft and sitting between the graft and the aortic wall.[37, 38] This enables usage of an off-the-shelf bifurcated or tube graft to be used for the aneurysm repair while allowing the graft to be positioned such that adequate sealing is obtained.[38] Chimney grafts are particularly useful when a patient with hostile anatomy requires urgent aneurysm repair but is not suitable for an open procedure.[37]

Data from the Australasian Vascular Audit suggests complex grafts represented 13 per cent of the grafts implanted in Australia during 2010 to 2014.[10]

Helical anchors are intended to replace the need for complex grafts. If helical anchors are available they would be used in conjunction with standard (tube or bifurcated) grafts.[13]

Comparator for Population 2

The proposed comparators for Population 2 (both for type 1A endoleak and migration) are:

- Revision EVAR/TEVAR including addition of component pieces and/or repositioning of stent graft, and/or aggressive ballooning i.e. angioplasty)
- Open repair

When a Type IA endoleak or graft migration is discovered, there are multiple options available to vascular surgeons to try to repair the leak. The stent should be repositioned if required.[11] It is recommended that balloon molding is attempted to seal the proximal zone of the graft. If this fails, then proximal extension of the graft, use of cuffs or conversion to a fenestrated graft are recommended. Conversion to open repair is recommended for persistent Type IA endoleak.[20]

The use of helical anchors is expected to replace the listed comparators[13] Expert advice is that, if available, helical anchors would be used before all of the listed comparators, including balloon molding.[11]

Rationale

International guidelines also recommended techniques such as embolisation with coils or glues as potential Type IA endoleak repair strategies; however, expert opinion is that these techniques are not routinely used in Australia.[20, 31]

Outcomes

Patient relevant

The Application (page 30) lists the following patient-relevant outcomes:[13]

Safety

- Device or procedure related adverse events
- Serious adverse events
- Procedure-related mortality

Effectiveness

- Freedom from Type IA endoleak or graft migration
- Sac regression
- Rate of reintervention
- Rate of Type IA endoleak and graft migration
- Rupture
- Aneurysm-related mortality
- Conversion to open repair
- Quality of life

Healthcare system

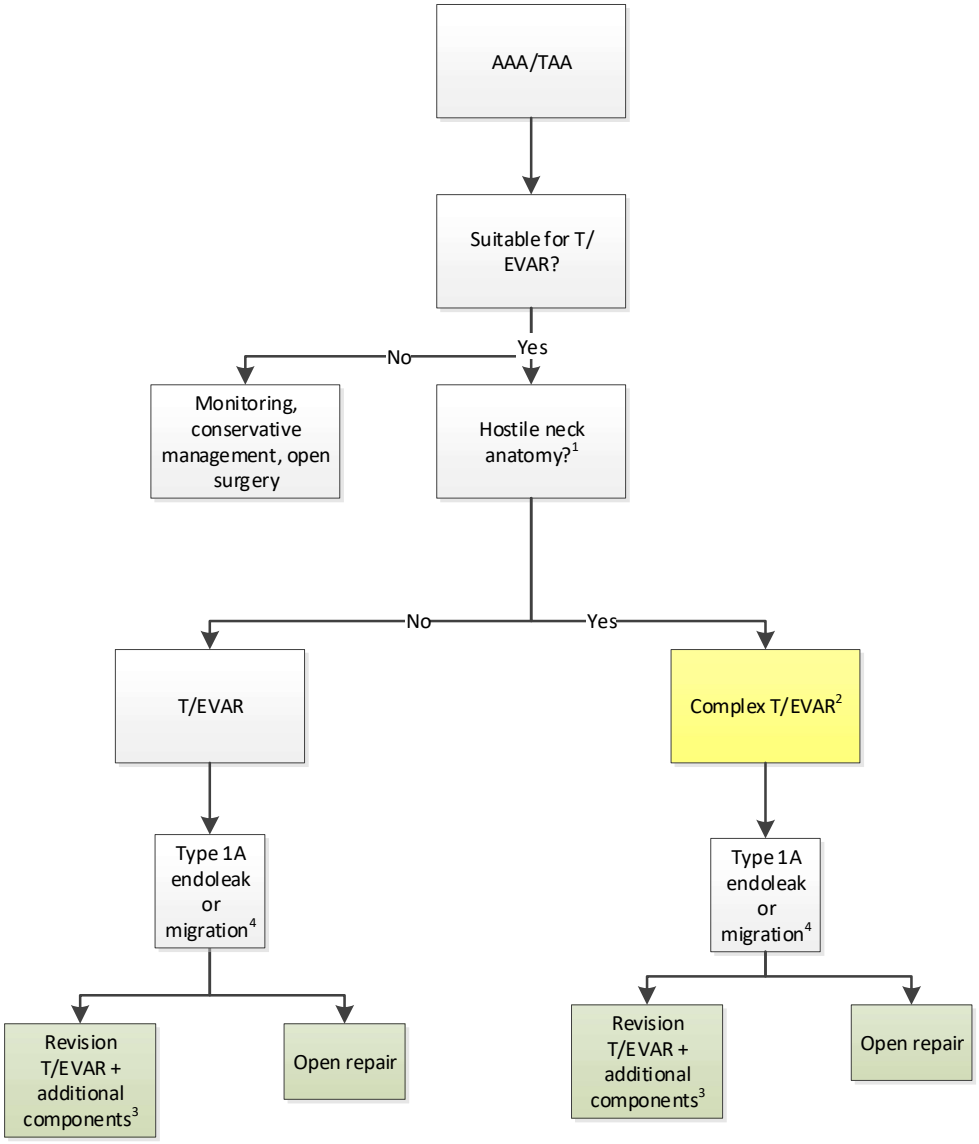
The following outcomes are proposed as being relevant to the Healthcare system

- Costs associated with the intervention and comparators including costs of the helical anchors, costs of stents, anaesthesia, pre-, peri- and post-procedure imaging, time to perform intervention and comparator techniques and all other costs
- Length of hospital stay and use of hospital resources
- Follow-up requirements (including ongoing imaging).

Current clinical management algorithm for identified population

The current clinical algorithm (adapted from the application documents) is provided in Figure 2.[13]

Figure 2 Current management algorithm for Populations 1, 2 and 3



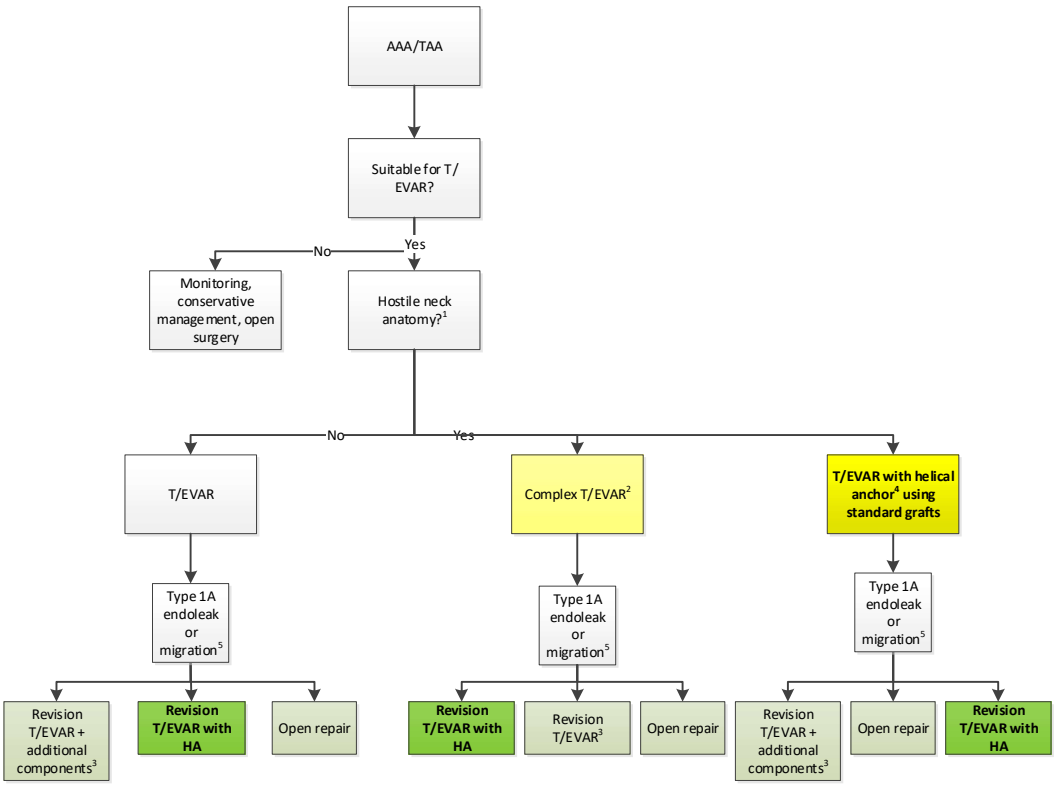
Source: Adapted from the Application documents (page 39). Note the figure has been simplified from the version provided by the Applicant to remove reference to other types of endoleak which are outside the scope of this PICO Confirmation. All information relevant to the proposed service is unchanged.

Note: Population 1 is highlighted in yellow, Population 2 is highlighted in green. 1: Hostile neck anatomy is defined as length <10 mm, diameter >28 mm, angulation >60 degrees or aortic neck is conical. 2: Complex T/EVAR refers to the use of fenestrated, branched or chimney grafts. 3: Additional components may include repositioning of the graft, aggressive ballooning, cuffs, extenders, converters. 4. Migration defined as movement of the endograft greater than 10 mm or any migration of the graft which necessitates any intervention or causes endoleaks.

Abbreviations: AAA = abdominal aortic aneurysm, TAA = thoracic aortic aneurysm, T/EVAR = thoracic endovascular aneurysm repair or endovascular aneurysm repair

Proposed clinical management algorithm for identified population

Figure 3 Proposed clinical management algorithm



Source: Adapted from the Application documents (page 39).
Note: Population 1 is highlighted in yellow, Population 2 is highlighted in green. The proposed intervention is shown in bold. 1: Hostile neck anatomy is defined as length <10 mm, diameter >28 mm, angulation >60 degrees or aortic neck is conical. 2: Complex T/EVAR refers to the use of fenestrated, branched or chimney grafts. 3: Additional components may include repositioning of the graft, aggressive ballooning, cuffs, extenders, converters. 4: In conjunction with simple tube or bifurcated grafts. 5. Migration defined as movement of the endograft greater than 10 mm or any migration of the graft which necessitates any intervention or causes endoleaks.
Abbreviations: AAA = abdominal aortic aneurysm, HA = helical anchors, TAA = thoracic aortic aneurysm, T/EVAR = thoracic endovascular aneurysm repair or endovascular aneurysm repair.

Proposed economic evaluation

The clinical claim is that use of helical anchors is at least non-inferior with respect to safety and effectiveness to the listed comparators (Application documents page 30).

If the results of the assessment find that the technology is non-inferior, a cost-minimisation analysis may be appropriate. However, if the technology is found to have superior safety or effectiveness then a cost-effectiveness or cost-utility analysis should be conducted.

PASC considered a cost-effectiveness analysis to be appropriate and suggested inclusion of sensitivity analyses investigating graft cost and durability.

Proposed item descriptor

The proposed MBS item descriptor is:

Category 3 – THERAPEUTIC PROCEDURES
Proposed item descriptor: ABDOMINAL OR THORACIC AORTIC ANEURYSM, transmural fixation of endograft to the aorta using helical anchors adjunct to endovascular aneurysm repair in patients: • With an aneurysm neck anatomy length <10mm, diameter >28 mm, angulation >60 degrees or aortic neck is conical for EVAR OR diameter ≥ 40mm, length <20 mm for TEVAR OR • Patients with a Type IA endoleak during or following previous aneurysm repair • Patients with a device migration following previous aneurysm repair, where migration is defined as movement of the endograft greater than 10 mm or any migration of the graft which necessitates any intervention or causes endoleaks. Fee: $TBC

PASC advised that the final MBS item descriptor may include a maximum number of anchors that can be used.

References

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