



Australian Government

Department of Health

Application Form

Trans-radial delivery of a dual-filter cerebral embolic protection system during transcatheter aortic valve implantation (TAVI)

(New and/or Amended Request for Public Funding)

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 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.

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): **REDACTED**

Corporation name: Boston Scientific

ABN: **REDACTED**

Business trading name: **REDACTED**

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

Percutaneous trans-radial delivery of a dual-filter cerebral embolic protection (CEP) system during transcatheter aortic valve implantation (TAVI) procedure for the reduction of peri-operative embolic ischaemic strokes.

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)

Embolic ischaemic strokes can occur in patients undergoing endovascular procedures. The origin of these embolic cerebrovascular events is variable and can include dislodged calcium particles, atherosclerotic plaque material, thrombus, valve and arterial wall tissue, and sheared interventional catheter coating material. When the embolic material (thrombus/debris) lodges in an artery and blocks the flow of blood, this leads to a type of ischaemic stroke. This is a serious event that can lead to serious debilitation or death.

Many endovascular procedures associated with structural interventions are known to be cardioembolic, including transcatheter aortic valve implantation/replacement (TAVI/TAVR), mitral valve repair/replacement (MVR), left atrial appendage closure (LAAC), valve in valve (VIV), and thoracic endovascular aortic repair (TEVAR). Given that the largest body of clinical evidence is from studies conducted in patients with severe, symptomatic aortic stenosis undergoing TAVI, this application focuses on the use of the percutaneous trans-radial delivery of a dual-filter CEP system as an adjunctive therapy for TAVI.

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 a percutaneous trans-radial delivery of a dual-filter CEP system designed to *capture* and *remove* debris that may enter the cerebral vascular system during the TAVI procedure. CEP system is comprised of two independent deployable filters with sizes suitable for the arteries that provide the main blood supply to the brain. The CEP system is inserted via the radial artery and delivers an intra-luminal filter in the common trunk of the branchiocephalic artery (proximal filter), and a second filter delivered in the proximal section of the left common carotid artery (distal filter), filtering approximately 90% of the blood flow to the brain. At the completion of the procedure, the filters and any captured debris are retrieved into the catheter and removed from the patient.

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

- Yes
 No

This application is in response to the Prosthesis List Advisory Committee (PLAC) recommendation for a health technology assessment (HTA) and for an evaluation of the comparative clinical effectiveness and cost-effectiveness of the proposed medical service by Medical Services Advisory Committee (MSAC).

(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

N/A

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): Insert billing code(s) here

Trade name of prostheses: Insert trade name here

Clinical name of prostheses: Insert clinical name here

Other device components delivered as part of the service: Insert description of device components here

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

Advice provided to the Applicant 23 May, 2019: The PLAC considered this application at the meeting of 16 May 2019 and the members agreed that the proposed medical service (i.e. percutaneous trans-radial delivery of a dual-filter CEP system) needs to undergo a HTA to inform advice on comparative clinical effectiveness and cost-effectiveness. In particular the PLAC is seeking advice on whether the use of the CEP system (as an adjunctive) delivers improvements in the outcomes of the TAVI procedure.

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian marketplace 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: 0.014 PCI guidewire for navigation

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: Embolic Protection Device

Manufacturer's name: Claret Medical

Sponsor's name: Boston Scientific

- (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 listing, registration or inclusion number: 319101

TGA approved indication(s), if applicable: Indicated for use as an embolic protection device to capture and remove embolic material (thrombus/debris) that may enter the cerebral vascular system during endovascular procedures.

TGA approved purpose(s), if applicable: Indicated for use as an embolic protection device to capture and remove embolic material (thrombus/debris) that may enter the cerebral vascular system during endovascular procedures. The diameters of the arteries at the sites of filter placement should be measured and the filters sized to the Proximal and Distal Target Vessels.

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

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

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.	Registry	First-in-man use of a novel embolic protection device for patients undergoing transcatheter aortic valve implantation. Naber et al 2012.	Patients (N=40) scheduled for TAVI were prospectively enrolled at three centres. The Claret CE Pro™ cerebral protection device was placed via the right radial/brachial artery prior to TAVI and was removed after the procedure. No procedural transient ischaemic attacks, minor strokes or major strokes occurred.	https://www.ncbi.nlm.nih.gov/pubmed/22403768	2012
2.	Registry	MISTRAL-I. Van Mieghem et al 2013. Histopathology of embolic debris captured during transcatheter aortic valve replacement.	Patients (N=40) underwent transcatheter aortic valve replacement (TAVR) with the use of a dual-filter based embolic protection device. Overall TAVR procedural success was obtained in all patients with the exception of 1 patient.	https://www.ncbi.nlm.nih.gov/pubmed/23652860	2013

	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***
3.	RCT	CLEAN-TAVI. Haussig et al 2016. Effect of a cerebral protection device on brain lesions following transcatheter aortic valve implantation in patients with severe aortic stenosis: the CLEAN-TAVI randomized clinical trial. NCT01833052.	Patients (N=100) were randomly assigned to undergo TAVI with a cerebral protection device (filter group) or without a cerebral protection device (control group). This study was a landmark RCT showing that the use of dual-filter CEP statistically reduces the number and volume of new lesions in the brain after TAVI when assessed by DW-MRI.	https://www.ncbi.nlm.nih.gov/pubmed/27532914	2016
4.	RCT	MISTRAL-C. Van Mieghem et al 2016. Filter-based cerebral embolic protection with transcatheter aortic valve implantation: the randomised MISTRAL-C trial. Dutch trial register-ID: NTR4236	Patients (N=65) were randomised 1:1 to transfemoral TAVI with or without the Sentinel CEP. Overall, 27% of Sentinel CEP patients and 13% of control patients had no new lesions. Ten or more new brain lesions were found only in the control cohort (in 20% vs. 0% in the Sentinel CEP cohort, p=0.03). The first study to show that patient neurocognitive outcomes were improved with the use of dual-filter CEP when measured by MoCA and MMSE tests.	https://www.ncbi.nlm.nih.gov/pubmed/27436602	2016.

	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***
5.	RCT	SENTINEL IDE. Kapadia et al 2017. Protection Against Cerebral Embolism During Transcatheter Aortic Valve Replacement. NCT02214277	Patients (N=363) undergoing TAVR were randomised to a safety arm (n = 123), device imaging (n = 121), and control imaging (n = 119). Strokes at 30 days were 9.1% in control subjects and 5.6% in patients with devices (p = 0.25) Study showing that peri-procedural neurologist adjudicated stroke is reduced by 63% when a dual-filter device is used.	https://www.ncbi.nlm.nih.gov/pubmed/27815101	2017
6.	Prospective	SENTINEL-UlM. Seeger et al 2017. Cerebral Embolic Protection During Transcatheter Aortic Valve Replacement Significantly Reduces Death and Stroke Compared With Unprotected Procedures.	A propensity scored matched pair analysis in 560 patients from a single academic institution showing that 7-day stroke is significantly reduced by 70% when dual-filter CEP is used routinely.	https://www.ncbi.nlm.nih.gov/pubmed/28917515	2017
7.	Prospective	Seeger et al 2019. Rate of peri-procedural stroke observed with cerebral embolic protection during transcatheter aortic valve replacement: a patient-level propensity-matched analysis.	Patients from the SENTINEL US IDE trial were combined with the CLEAN-TAVI and SENTINEL-UlM study in a patient-level pooled analysis (N = 1306). In patients undergoing TAVR with dual-filter CEP, procedural all-stroke was significantly lower compared with unprotected procedures [1.88% vs. 5.44%, odds ratio 0.35, 95% confidence interval (CI) 0.17-0.72, relative risk reduction 65%, P = 0.0028].	https://www.ncbi.nlm.nih.gov/pubmed/30590554	2019

	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***
8.	Prospective	Kroon et al 2019. Early Clinical Impact of Cerebral Embolic Protection in Patients Undergoing Transcatheter Aortic Valve Replacement.	The rates of neurological events in patients with or without cerebral embolic protection (CEP) during transcatheter aortic valve replacement (TAVR) were compared. CEP was associated with significantly fewer neurological events at 24 hours after TAVR (odds ratio, 0.20; 95% CI, 0.06-0.73; P=0.015).	https://www.ncbi.nlm.nih.gov/pubmed/31195822	2019

* 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.

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.	RCT	PROTECT TAVI - Prospective Randomized Outcome Study in TAVI Patients Undergoing Peri-procedural Embolic Cerebral Protection With the Claret Sentinel™ Device NCT02895737	This prospective, randomized study was designed to analyse the difference of cerebral embolization in patients undergoing transcatheter aortic valve implantation with balloon-expandable vs. self-expandable valves by using a cerebral protection system (Claret Sentinel™ Device). Estimated enrolment n=328 and currently recruiting.	https://clinicaltrials.gov/ct2/show/NCT02895737	September 2019
2.	Registry	SENTINEL-H. Histopathology of Embolic Debris Captured During Transcatheter Aortic Valve Replacement. NCT02255851	The SENTINEL Post-Market Registry is a prospective, multi-center, registry using the CE-Marked Sentinel System in subjects with severe symptomatic calcified native aortic valve stenosis indicated for TAVR. Subjects enrolled in the registry will undergo TAVR + Sentinel. Completed; data are not yet available.	https://www.clinicaltrials.gov/ct2/show/NCT02255851	2018

* 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):**

Applicant advised that this is not required as the application has been referred from PLAC.

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

Not relevant.

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

Applicant advised that this is not required as the application has been referred from PLAC.

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

No other Sponsor's or manufacturers produce similar dual-filter CEP systems.

- 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: TBC

Telephone number(s): TBC

Email address: TBC

Justification of expertise: TBC

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), INTERVENTION, COMPARATOR, OUTCOME (PICO)

A summary of the PICO components to assess the proposed medical service, trans-radial delivery of a dual-filter CEP system during TAVI procedure for the reduction of peri-operative embolic ischaemic strokes, is in Table 1.

Table 1 PICO components to assess dual-filter CEP system

Component	Description
Patients	Patients with symptomatic severe aortic stenosis undergoing TAVI*
Intervention	Percutaneous trans-radial dual-filter cerebral embolic protection (CEP) system
Comparator	No filter
Outcomes	<p>Safety Outcomes: Procedural complications</p> <p>Clinical Effectiveness Outcomes: Clinical stroke and/or neurocognitive dysfunction post-procedure Peri-procedural ischaemic stroke Mortality Total new lesion volume detected by MRI New cerebral lesions detected by MRI</p> <p>Quality of life Health related quality of life</p> <p>Cost-effectiveness Resource utilisation (surgical costs, follow-up imaging [CT, MRI], rehabilitation, pain management medication) Quality adjusted life year</p> <p>Healthcare resources: Length of hospital stay in Australia Cost of consumables</p>

* Patients meeting the MBS eligibility criteria for TAVI procedure (MBS item 38495)

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:

The proposed medical service, dual-filter CEP system, is to be used adjunctively during the TAVI procedure (MBS item 38495) for the reduction of peri-operative embolic ischaemic strokes. The TAVI procedure is a minimally invasive procedure for severe symptomatic aortic stenosis which is a narrowing or obstruction of the aortic heart valve caused by plaque build-up. During the TAVI procedure, plaque (embolic debris) can break away from the artery or valve and float loosely in the bloodstream to smaller arteries in the brain and block them thereby cutting off the blood and oxygen supply. Blocked blood and oxygen flow in the brain can cause a stroke, which could result in brain damage and could be fatal. The dual-filter CEP system is designed to capture and remove debris dislodged during TAVI, reducing the risk of peri-operative embolic ischaemic strokes.

Prevalence of aortic stenosis in Australia has not experienced significant fluctuations from 2015 until 2018, remaining close to 5.4% during this period. It has been estimated however, that prevalence of the disease will gradually increase by 0.1% each year from 2019 onwards (Data on file). In this regard, it is important to note that the potential for stroke is one of the deterrents that may lead a physician to choose to not perform a TAVI procedure on a patient with severe symptomatic aortic stenosis. The TAVI procedure alone carries an inherent risk of stroke, where the incidence of clinical stroke 30-days after TAVI procedure can vary between 2 and 10% (Tamburino 2011; Eltchaninoff 2011; Leon 2010; Nuis 2012).

According to the Medicare Benefits Schedule, there have been a total of 451 services associated with TAVI procedures (MBS item 38495) from July 2017 to June 2018. With such a variation in reported stroke rates (stated above), it is important to note that stroke rates are also considered to be underestimated due to the inconsistency in neurologist assessed stroke, which is further confounded by controversial and evolving stroke definitions over the last decade.

Stroke is one of Australia's biggest killers and a leading cause of disability (AIHW 2018); 65% of stroke survivors suffer a disability which impedes their ability to carry out daily living activities unassisted (Deloitte Access Economics 2013). In addition to overt stroke, procedure-related emboli can cause silent ischaemic brain lesions or microinfarcts, potentially leading to cognitive decline and/or increased risk of future clinical stroke and mortality (Smith 2012). The financial cost of stroke in Australia is estimated to be \$5 billion each year (Deloitte Access Economics 2013).

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 who would be eligible for the proposed medical service would be patients who are undergoing the TAVI procedure; patients with symptomatic aortic stenosis deemed too high risk for surgical aortic valve replacement (SAVR) and who meet MBS eligibility criteria for TAVI (MBS item 38495). The dual-filter CEP system is used as an adjuvant procedure to TAVI. During the TAVI procedure, embolic material that is dislodged, is collected and removed by the dual-filter CEP system. A key opinion leader estimate is that approximately 90% of the patients who are eligible for TAVI would be eligible for the CEP system. Eligibility is largely dependent on the patient's aortic arch anatomy fitting the sizing requirements for the CEP system: the brachiocephalic trunk and left common carotid artery should range between 9 and 15 mm and 6.5 and 10 mm, respectively, without excessive tortuosity or >70% obstructive atherosclerotic disease (Van Mieghem et al 2016).

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):

For a patient to receive the proposed medical service, the patient would have been pre-assessed and diagnosed with severe aortic stenosis, deemed too high risk for SAVR and would be have been considered eligible for the TAVI procedure based on the eligibility criteria as per MBS item 38495. Computed tomography scans are performed to determine the size of the aortic annulus, the access vessels, the brachiocephalic trunk, and the left common carotid artery. It is during the TAVI procedure in which the patient will receive the CEP system. See Appendix A - Figure 4.

PART 6b – INFORMATION ABOUT THE INTERVENTION

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

The details of the key components and clinical steps involved in delivery the intervention specially refer to the use of Sentinel™ Cerebral Protection System (Claret Medical™); [Sentinel™ CPS].

Sentinel™ CPS is a percutaneously delivered embolic protection device, designed to capture and remove debris dislodged during endovascular procedures such as TAVI. Sentinel™ CPS utilises an embolic filter delivered to the brachiocephalic artery (Proximal Filter), and a second embolic filter delivered to the left common carotid artery (Distal Filter) (Figure 1). At the completion of the procedure, the filters and debris are recaptured into the catheter and removed from the patient. Sentinel™ CPS consists of a 6 French catheter with deployable Proximal and Distal Filters, an Articulating Sheath and an integral handle assembly. The Articulating Sheath tip, Proximal Sheath tip, Proximal Filter hoop, Distal Filter hoop and Distal Filter tip are radiopaque to enable visualization during use.



Figure 1 Illustration of Sentinel placement

Procedural Use - Delivery and Deployment

1. Using standard interventional technique, place a 6 French introducer sheath into the radial or brachial artery of the patient's right arm.
2. Backload a floppy tip 0.014" coronary guidewire into the Distal Filter Tip located at the distal end of the Sentinel™ CPS until the guidewire tip is located just inside the distal tip of the Sentinel™ CPS catheter.
3. Introduce the Sentinel™ CPS into the introducer sheath.
4. In the patient's right arm, advance the guidewire relative to the Sentinel™ CPS until the distal tip of the guidewire is a minimum of 10 cm beyond the distal tip of the Sentinel™ CPS using fluoroscopic guidance.
5. Advance the Sentinel™ CPS distally until it contacts the introducer sheath hemostasis valve. Gently advance the Sentinel™ CPS until it is fully inserted into the introducer hemostasis valve.
6. Advance the Sentinel™ CPS and the guidewire together using standard interventional technique until the Proximal Filter is in the intended target location in the brachiocephalic artery with the Articulating Sheath section of the catheter extending down the ascending aorta. Should the catheter tip extend down the descending aorta, pull the system back and rotate to advance down the ascending aorta.
7. Deploy the Proximal Filter by holding the Front Handle in a fixed position and slowly retracting the Proximal Filter Slider fully.
8. Confirm proper Proximal Filter position using fluoroscopy. The Proximal Filter should be positioned in the brachiocephalic artery to prevent any debris from reaching the right carotid artery.
9. If the filter position is not optimal, the filter may be retrieved and repositioned up to two times. This may be done by holding the Front Handle in a stationary position and advancing the Proximal Filter Slider until the Proximal Filter is re-sheathed. The Proximal Filter may then be repositioned by advancing or retracting the catheter until optimal positioning is achieved. Finally the Proximal Filter is redeployed by retracting the Proximal Filter Slider while holding the Front Handle in a fixed position.
10. Confirm filter-to-vessel wall apposition using fluoroscopy, and ensure that the Proximal Filter and Proximal Sheath do not move after placement.
11. Withdraw the guidewire until the tip is located just within the distal tip of Sentinel catheter.
12. Loosen the Front Handle Lock to facilitate positioning of the Articulating Sheath.
13. Position the Articulating Sheath by manipulating the Rear Handle relative to the Front Handle in order to position the catheter tip. Rotate the Articulation Knob on the Rear Handle in the direction of the arrows in order to deflect the tip of the Articulating Sheath as necessary toward the left common carotid artery ostium.
14. Advance the 0.014" guidewire beyond the distal tip of the Articulating Sheath in order to place the guidewire in the left common carotid artery.
15. Position the Articulating Sheath so that the curvature matches the brachiocephalic artery – Aorta – Left Common Carotid Artery junction and is pulled up to the carina between the two vessels.
16. Secure the position of the Articulating Sheath by tightening the Front Handle Lock.

17. Loosen the Rear Handle Lock and advance the Distal Filter under fluoroscopy by pushing the Distal Filter Slider forward until the Distal Filter frame is fully expanded and apposed to the vessel wall. The Distal Filter should be positioned just beyond the Articulating Sheath tip and movement should be minimized once it is fully expanded in the vessel.
18. Confirm filter-to-vessel wall apposition of the distal filter using fluoroscopy.
19. Tighten the Rear Handle Lock.
20. Cover the exposed portion of the Sentinel™ CPS with a drape to prevent movement during subsequent endovascular procedures.

Procedural Use – Retrieval

1. Loosen the Rear Handle Lock.
2. Recover the Distal Filter using one of the following two methods:
 - a. Full Enclosure Recovery: Gently withdraw the Distal Filter Slider relative to the Rear Handle until the radiopaque Distal Filter Tip is flush with the Radiopaque Articulating Sheath Tip Marker as visualized on fluoroscopy. Tighten the Rear Handle Lock. If resistance is felt during Distal Filter recovery, or if it is believed that the Distal Filter is excessively full, follow the Partial Enclosure Recovery method detailed below.
 - b. Partial Enclosure Recovery: Gently withdraw the Distal Filter Slider relative to the Rear Handle until the Distal Filter Radiopaque Hoop is collapsed inside the Articulating Sheath tip as visualized on fluoroscopy. Tighten the Rear Handle Lock.
3. Loosen the Front Handle Lock and withdraw the Articulating Sheath tip from the left common carotid artery by manipulating, straightening, rotating, and advancing or withdrawing the Rear Handle and rotating the Articulation Knob until the Articulating Sheath tip is straight and is within the aorta.
4. Advance the Articulating Sheath completely by advancing the Rear Handle until the Articulation Knob contacts the Front Handle Lock to prevent interference with the Proximal Sheath or Proximal Filter during Proximal Filter retrieval. Tighten the Front Handle Lock.
5. Re-sheath the Proximal Filter by holding the Front Handle in a stationary position and slowly advancing the Proximal Filter Slider until the Proximal Sheath Radiopaque Marker meets the Articulating Sheath as visualized on fluoroscopy. Minimize retracting or advancing the Front Handle during this step. Vessel damage may occur or debris may be lost should the Proximal Filter be moved when in the deployed state.
6. Advance the guidewire prior to withdrawal of the Sentinel™ CPS. Withdraw the catheter system while using fluoroscopy.

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

The device used to perform the proposed medical service, does include a registered trademark component (Sentinel™), which is a dual-filter cerebral embolic protection device available in Australia.

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?

The proposed medical service has a prosthesis component to it and involves the delivery of the application of the dual-filter CEP system designed to capture and remove debris dislodged during the TAVI procedure. The patients who receive the proposed medical service during the TAVI procedure, follow the same clinical management as a patient who did not receive the proposed medical service during TAVI.

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):

The proposed medical service is intended to be performed once during endovascular procedures such as TAVI. There are no current limitations on the provision of the proposed medical service with respect to accessibility above and beyond the accessibility of the TAVI procedure.

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

The healthcare resources required at the same time as the proposed medical service include administration of anaesthesia (patients are under general anaesthesia) and hospitalisation.

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

The proposed medical service is performed by either a cardiothoracic surgeon or interventional cardiologist performing the TAVI procedure.

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

N/A

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

Physicians conducting TAVI require accreditation which is managed by the TAVI Accreditation Committee: <https://tavi.org.au/>

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:

The training for physicians is done by the Structural Heart Clinical Specialist and includes a 30-45min didactic session with demonstration. The physician is deemed independent after performing 10 cases with clinical support.

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

- Inpatient private hospital (admitted patient)
- Inpatient public hospital (admitted patient)
- Private outpatient clinic
- Public outpatient clinic
- Emergency Department
- Private consulting rooms - GP
- Private consulting rooms – specialist
- Private consulting rooms – other health practitioner (nurse or allied health)
- Private day surgery clinic (admitted patient)
- Private day surgery clinic (non-admitted patient)
- Public day surgery clinic (admitted patient)
- Public day surgery clinic (non-admitted patient)
- 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 procedures are performed in the hospital inpatient setting (private and public) with post-procedure hospitalisation and observation.

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):**

The nominated comparator is 'no filter': meaning no CEP filter system used during the TAVI procedure. There are currently no alternative filter CEP systems available or used during the TAVI procedure in Australia. It is expected that most TAVI procedures (~90%) will be performed with the dual-filter CEP system should it be listed on the MBS (KOL opinion).

Alternative options to the proposed medical service, include the systems that use *deflection* of embolic debris such as Keystone Heart TriGuard and Transverse Medicals 'PointGuard' system. KOL opinion suggested that this would not be an appropriate comparator for the purposes of this application because their mechanism is different to the filter devices. These devices *deflect* embolic material as opposed to *capture* and *collect* debris from the patient, as does the proposed medical service. The deflection of material could potentially lead it to be diverted into the renal or mesenteric arteries with associated clinical sequelae. Therefore, the capture, retrieval and removal from the body is a key benefit that can only be achieved by using the dual-filter CEP system.

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

Yes (please list all relevant MBS item numbers below)
 No

N/A

- 40. Define and summarise the current clinical management pathway/s 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 management for a patient who receives the proposed medical service would be the same as a patient who receives the TAVI procedure without the dual-filter CEP system. After the procedure, the patient remains in hospital for approximately 5 days for post-procedure observation. Should the patient display signs and symptoms of a stroke within 72 hours of the procedure, a CT or MRI is scheduled to diagnose if a peri-procedural stroke has occurred. The strokes prevented by using CEP system are captured within the first 72 hours post-procedure. Strokes occurring ≥ 7 days post-procedure are considered to not be procedure related. A patient who displays no signs or symptoms of a stroke during the hospital stay can be discharged with no imaging required. A high proportion of patients undergoing TAVI could experience silent ischaemic strokes. These would potentially go unnoticed and would only be picked up on a scan which is not routinely performed.

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

In addition to (i.e. it is an add-on service)
 Instead of (i.e. it is a replacement or alternative)

- (b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:**

N/A

- 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 39 as baseline):**

As mentioned in Q40, the management for a patient who received the proposed medical service would be the same as a patient who had the TAVI procedure without the dual-filter CEP system. However, given the prevention of stroke with the dual-filter CEP system versus no filter device, it is expected that resource utilisation associated with stroke management would be decreased.

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):**

Compared with no filter, the insertion of the dual-filter CEP system designed to capture and remove debris dislodged during TAVI is expected to result in superior effectiveness (functional) outcomes with better safety outcomes.

- 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:

Procedural complications

Clinical Effectiveness Outcomes:

Clinical stroke and/or neurocognitive dysfunction post-procedure

Peri-procedural ischaemic stroke

Mortality

Total new lesion volume detected by MRI

New cerebral lesions detected by MRI

Quality of life

Health related quality of life

Cost-effectiveness

Resource utilisation (surgical costs, follow-up imaging [CT, MRI], rehabilitation, pain management medication)

Quality adjusted life year

Healthcare resources:

Length of hospital stay in Australia

Cost of consumables

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

The proposed population is for patients currently eligible for TAVI on the MBS, defined as patients with symptomatic severe aortic stenosis deemed too high risk for surgical aortic valve replacement (SAVR).

The prevalence of symptomatic severe aortic stenosis in Australia has been estimated in previous MSAC applications (MSAC applications 1361, 1361.1, 1361.2 and 1552) based on Osnabrugge (2013). Osnabrugge (2013) conducted a meta-analysis and modelling study of studies on decision making in aortic stenosis (AS). A pooled prevalence of 3.4% was reported for severe AS in people aged 75 years and over, of whom 75.6% were symptomatic (Figure 2). Assuming 40.5% of symptomatic severe AS patients are ineligible for SAVR, from Osnabrugge (2013), results in an estimated prevalence of 2.6% (3.4%×75.6%) for symptomatic severe AS in a population aged 75 or over.

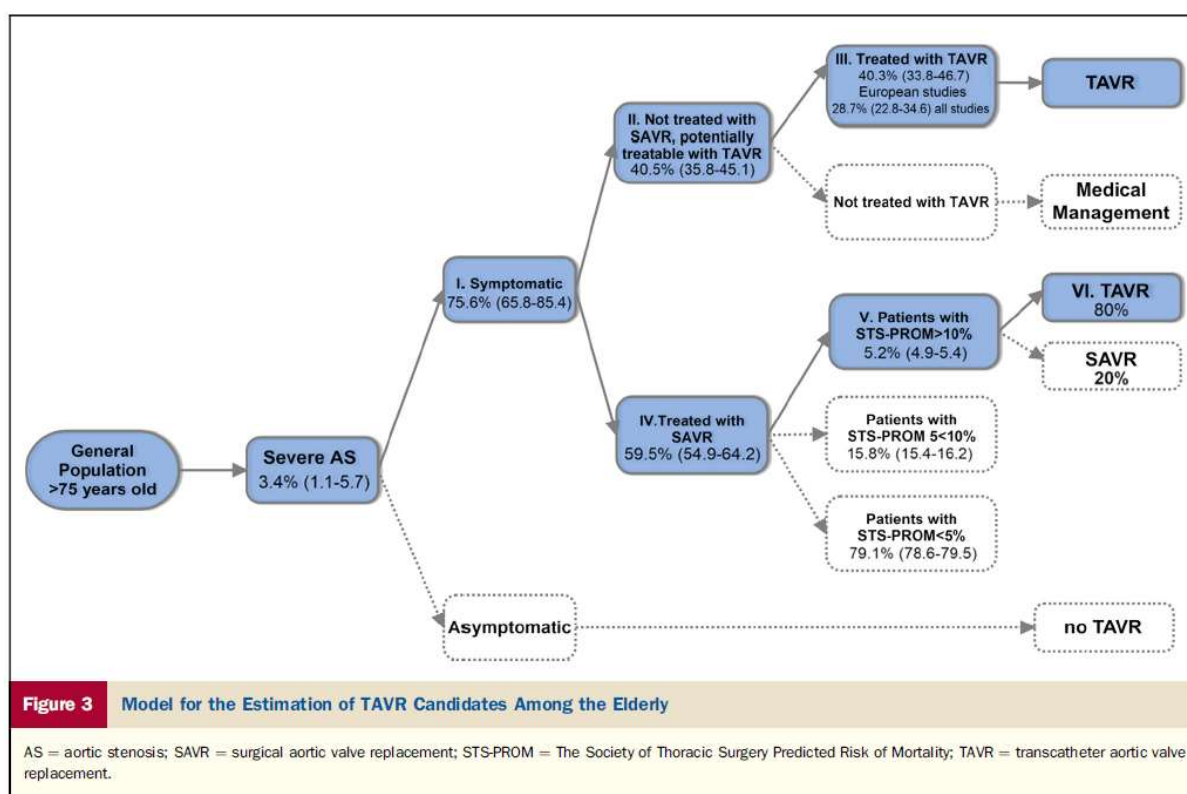


Figure 2 Model for the Estimation of TAVR Candidates Among the Elderly from Osnabrugge (2013)

A similar meta-analysis of disease prevalence, severity, decision making, and survival studies in patients with AS was conducted in De Sciscio (2017). De Sciscio (2017) reported a prevalence of AS of 4.5% in people aged ≥60 years; 2.8% (95% CI 1.4%-4.1%) in people aged 60 to 74 years and 13.1% (95% CI 8.2%-17.9%) in people aged ≥75 years (Figure 3). 19.9% of AS patients were reported as having severe AS, of whom 71.2% were symptomatic. Therefore, based on De Sciscio (2017), a prevalence of symptomatic severe AS of 0.4% (2.8%×19.9%×71.2%) is estimated in patients aged 60 to 74 years and 1.9% (13.1%×19.9%×71.2%) in patients aged ≥75 years.

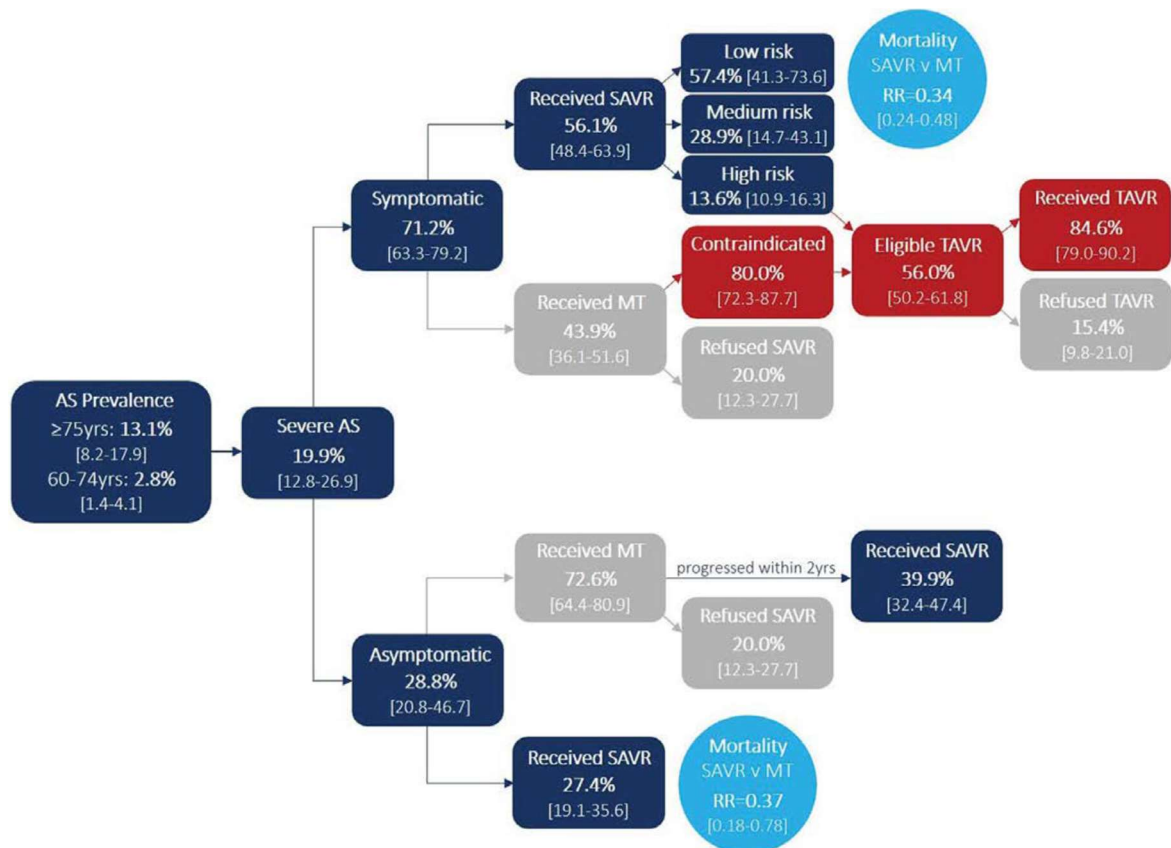


Figure 3 Map of disease progression to aortic valve replacement from De Sciscio (2017)

Based on De Sciscio (2017) and Osnabrugge (2013), the prevalence of symptomatic severe AS in patients aged ≥ 75 years is estimated between 1.9-2.6%. Only a proportion of symptomatic severe AS patients are deemed too high risk for SAVR whilst remaining eligible for TAVI. It is estimated, based on De Sciscio (2017), 35% ($43.9\% \times 80\%$; see Figure 3) of patients with symptomatic severe AS will be ineligible for SAVR, 56% of whom would be eligible for TAVI. As such, the prevalence of the proposed population is estimated to be 0.1% ($0.4\% \times 35\% \times 56\%$) in patients aged 60 to 74 years and 0.4% ($1.9\% \times 35\% \times 56\%$) in patients aged ≥ 75 years

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

The dual-filter CEP system is intended once per TAVI procedure.

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

It is expected dual-filter CEP system will be required once per TAVI procedure. Due to low repeat procedure rates Patients eligible for TAVR typically get one per lifetime

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

TAVI was listed on the MBS in December 2017. Over the first 11 months of listing, December 2017 to October 2018 (latest data available), 899 MBS services were accessed for TAVI procedures. Figure illustrates the monthly utilisation of MBS item 38495 (TAVI) since listing.

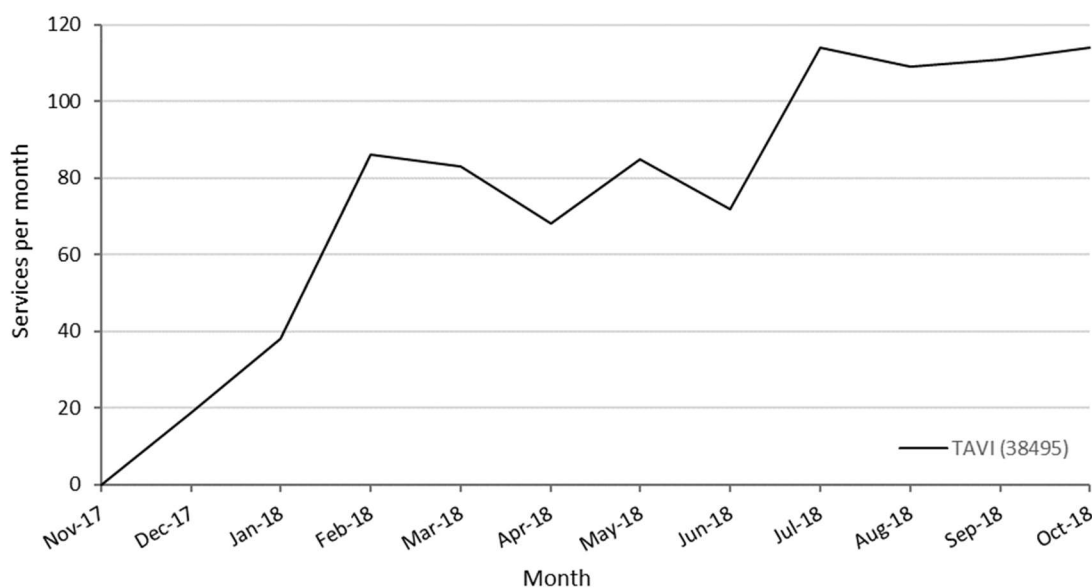


Figure 4 Monthly utilisation of MBS item 38495 services for TAVI procedures

TAVI utilisation in Year 1 of dual-filter CEP listing is estimated based on monthly utilisation between July 2018 and October 2018 as utilisation appears to plateau over this period. Over this period an average of 112 TAVI services were accessed per month, equivalent to 1,344 (112×12) procedures over 12 months. KOL estimates approximate 90% of patients eligible for TAVI would be eligible for dual-filter CEP adjunct to TAVI. As such, it is estimated 1,210 (1,344×90%) patients will be eligible for dual-filter CEP adjunct to TAVI in Year 1. An uptake rate of REDACTED% is assumed for dual-filter CEP in Year 1, based on Applicant experience in global markets. Applying REDACTED% uptake, it is estimated REDACTED (1,210×REDACTED%) dual-filter CEP adjunct to TAVI procedures will be conducted in Year 1 (Table 2).

Table 2 Estimated utilisation of dual-filter CEP adjunct to TAVI in the Year 1 of MBS listing

Row	Parameter	Year 1	Source / calculation
A	Estimated MBS services for TAVI	1,344	Calculated ^a
B	Proportion of TAVI patients eligible for dual-filter CEP	90%	KOL estimate
C	Estimated patients eligible for dual-filter CEP adjunct to TAVI on the MBS	1,210	A×B
D	Uptake rate	REDACTED%	Assumption
E	Estimated MBS services for dual-filter CEP adjunct to TAVI	REDACTED	C×D

^a Estimated annual utilisation of TAVI based on monthly TAVI utilisation between July 2018 and October 2018. 112 services a month x 12 months = 1,344 services.

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:

Assuming constant TAVI utilisation over the first 4 years of dual-filter CEP adjunct to TAVI listing and linearly increasing uptake from REDACTED% in Year 1 to REDACTED% in Year 4, it is estimated REDACTED dual-filter CEP adjunct to TAVI procedures will be performed in Year 2, REDACTED in Year 3 and REDACTED in Year 4 (Table 3).

Table 3 *Estimated utilisation of TAVI+CEP over the next 3 years of MBS listing (subsequent to Year 1)*

Row	Parameter	Year 1	Year 2	Year 3	Year 4	Source / calculation
A	Estimated MBS services for TAVI	1,344	1,344	1,344	1,344	Calculated ^a
B	Proportion of TAVI patients eligible for dual-filter CEP	90%	90%	90%	90%	KOL estimate
C	Estimated patients eligible for dual-filter CEP adjunct to TAVI on the MBS	1,210	1,210	1,210	1,210	A×B
D	Uptake rate	REDACTED%	REDACTED%	REDACTED%	REDACTED%	Assumption
E	Estimated MBS services for dual-filter CEP adjunct to TAVI	REDACTED	REDACTED	REDACTED	REDACTED	C×D

^a Estimated annual utilisation of TAVI based on monthly TAVI utilisation between July 2018 and October 2018. 112 services a month x 12 months = 1,344 services.

It is acknowledged that projected TAVI utilisation is uncertain given the short duration of MBS listing. MSAC application 1361 estimated TAVI utilisation would be between 700-800 per year over the first 5 years of listing (PSD MSAC 1361, pg. 5). Utilisation has already exceeded these estimates with 899 TAVI services reported over the first 11 months of listing. As noted in the PSD for MSAC application 1361, it is likely this additional utilisation is a result of a prevalent pool of patients previously identified as SAVR ineligible becoming eligible for TAVI upon MBS listing. This prevalent patient issue will be addressed in the forthcoming submission-based assessment.

PART 8 – COST INFORMATION

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

For transparency, a procedure cost has been estimated for both dual-filter CEP adjunct to TAVI and TAVI without the dual-filter CEP. Procedure costs are estimated including; device costs, medical service costs and hospitalisation costs.

The dual-filter CEP system benefit is **REDACTED**, whilst TAVI devices are currently listed on the Prostheses List for \$22,932 (July 2019). As such, dual-filter CEP adjunct to TAVI procedures are estimated to be associated with total device benefit of **REDACTED**.

Current MBS medical service items assumed to be associated with TAVI procedures are presented in Table 4, including; the TAVI procedure service, initiation and management of anaesthesia service and time unit anaesthesia service. Note: for anaesthesia time units, a procedure duration of 81 minutes is estimated for dual-filter CEP adjunct to TAVI compared to 68 minutes for TAVI without the dual-filter CEP based on the SENTINEL IDE trial, as addressed in Question 52.

Table 4 Medical service costs associated with TAVI+CEP

MBS item/s	Description	Fee
38495	TAVI, for the treatment of symptomatic severe aortic stenosis, performed via transfemoral delivery, unless transfemoral delivery is contraindicated or not feasible, in a TAVI Hospital on a TAVI Patient by a TAVI Practitioner – includes all intraoperative diagnostic imaging that the TAVI Practitioner performs upon the TAVI Patient.	\$1,455.10
20770	INITIATION OF MANAGEMENT OF ANAESTHESIA for procedures on major upper abdominal blood vessels.	\$301.50
23051, 23052, 23053	1:01 HOURS TO 1:15 HOURS.	\$100.50
23061, 23062, 23063	1:16 HOURS TO 1:30 HOURS.	\$120.60

In addition to these MBS items a new item is proposed for the insertion of dual-filter CEP (see Question 53). The proposed fee for this item is based on the additional procedure time compared to a TAVI procedure without dual-filter CEP, 81 minutes versus 68 minutes (see Question 52; SENINEL IDE). The use of a dual-filter CEP device is estimated to increase the procedure duration by 13 minutes (81-68), equivalent to 19.1% (13/68). Therefore, a fee of \$278.18 is proposed for the insertion of dual-filter CEP, representing 19.1% of the current TAVI fee (MBS item 38495).

A hospitalisation cost is estimated based on AR-DRG code F04C for 'Cardiac Valve Procedures W CPB Pump W/O Invasive Cardiac Invest, Minor Comp'. The Private Hospital Data Bureau (PHDB) annual report 2016-17 reported an average hospital charge of \$36,660 per separation. Excluding the average prostheses charge for this AR-DRG, \$7,169, results in an estimated hospitalisation cost of \$29,491 per separation (Table 5). The same hospitalisation cost is assumed for TAVI procedures with and without adjunct dual-filter CEP.

Table 5 AR-DRG hospitalisation costs associated with cardiac valve procedures, PHDB annual report 2016-17

AR-DRG	Description	Separations (ALOS)	Average hospital charge (incl. prostheses)	Average prostheses charge	Average hospital charge (excl. prostheses)
F04A	Cardiac Valve Procedures W CPB Pump W/O Invasive Cardiac Invest, Major Comp	197 (22.03)	\$58,089	\$12,105	\$45,984
F04B	Cardiac Valve Procedures W CPB Pump W/O Invasive Cardiac Invest, Interm Comp	1,342 (12.06)	\$43,873	\$9,595	\$34,278
F04C	Cardiac Valve Procedures W CPB Pump W/O Invasive Cardiac Invest, Minor Comp	2,110 (9.47)	\$36,660	\$7,169	\$29,491

Abbreviations: ALOS, average length of stay; CPB, cardiopulmonary bypass; PHDB, Private Hospital Data Bureau.

Hospitalisation costs are assumed to account for consumables associated with TAVI procedures. However, it is acknowledged that dual-filter CEP insertion is associated with an additional consumable, a single guidewire per procedure. A single guidewire is estimated to cost **REDACTED**, based on the approximate cost of **REDACTED** for a 5 pack of Choice Extra Support Guide Wires (Applicant estimate). This cost is explicitly added in estimating the cost of a TAVI procedure with adjunct dual-filter CEP.

A total cost of **REDACTED** is estimated per TAVI procedure with adjunct dual-filter CEP compared to \$54,240 per TAVI procedure without dual-filter CEP (Table 6), an additional cost of **REDACTED** per procedure.

Table 6 Estimated costs associated with TAVI+CEP procedures

Row	Parameter	TAVI+CEP	TAVI alone	Source / calculation
A	CEP device benefit	\$REDACTED	-	Applicant
B	TAVI device benefit	\$22,932	\$22,932	Prostheses List July 2019
C	Medical service costs	\$2,155.38	\$1,857.10	D+F+G
D	TAVI service cost	\$1,455.10	\$1,455.10	MBS item 38495
E	Dual-filter CEP service cost	\$278.18	-	Proposed MBS item
F	Initiation and management of anaesthesia	\$301.50	\$301.50	MBS item 20770
G	Time units for anaesthesia	\$120.60	\$100.50	MBS item 23051
H	Hospitalisation costs ^a	\$29,491.18	\$29,450.42	AR-DRG code F04C
I	Guidewire for insertion of dual-filter CEP	REDACTED	-	Applicant
J	Total cost of procedure	REDACTED	\$54,239.52	A+B+C+H

^a AR-DRG code F04C related to Cardiac Valve Procedures W CPB Pump W/O Invasive Cardiac Invest, Minor Comp. A total hospital cost of \$36,660 was reported for AR-DRG code F04C in the Private Hospital data Bureau Annual Report 2016-17. Prostheses costs associated with AR-DRG code F04C were subsequently removed so as to avoid double counting resulting in an applied hospitalisation cost of \$29,491, i.e. \$36,660 - \$7,169 = \$29,491.

The cost of TAVI alone has previously been estimated in MSAC application 1361.2 for Transcatheter Aortic Valve Implantation via Transfemoral Delivery (TAVI) at the 30-31 March 2016 MSAC meeting. This application estimated a cost of \$64,191.72 per TAVI procedure (MSAC Application No. 1361.2 PSD, Table 1). This cost estimate included a proposed TAVI device cost of \$33,348, significantly higher than the current prostheses list TAVI device cost, \$22,932. Applying the current TAVI device cost results in an estimated cost of \$53,775.72 (\$64,191.72-\$33,348+\$22,932) per TAVI procedure.

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

A procedure duration of between 1-1.5 hours for the TAVI procedure was reported in the application form for MSAC application no. 1552. A similar procedure duration of 60 minutes was reported for TAVI procedures in the PSD for MSAC application No. 1361.2.

SENTINEL-H, a prospective, multi-centre, international registry, reported a median time for dual-filter CEP placement of 4 minutes (SD: 6 minutes). SENTINEL IDE, a randomised study, estimated procedure durations of 83.5 minutes, 78.0 minutes and 68.0 minutes for the device arm (dual-filter CEP adjunct to TAVI), safety arm (dual-filter CEP adjunct to TAVI) and control arm (TAVI without dual-filter CEP) respectively. This is equivalent to an incremental duration for dual-filter CEP insertion of 10 (78.0-68.0) minutes for the safety arm and 15.5 (83.5-68.0) minutes for the device arm. Applying a weighted average of the device and safety arms results in a procedure duration of 80.7 minutes for dual-filter CEP adjunct to TAVI, including a duration of 12.7 (80.7-68.0) minutes for dual-filter CEP insertion.

As such, it is expected that the insertion of the dual-filter CEP procedure is estimated to take 4-13 minutes in addition to the TAVI procedure.

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: Proposed item descriptor: Percutaneous trans-radial delivery of dual-filter cerebral embolic protection (CEP) system during transcatheter aortic valve implantation (TAVI) for the reduction of post-operative embolic ischaemic strokes Fee: \$278.18 (see Question 51 for fee calculation)

APPENDIX A

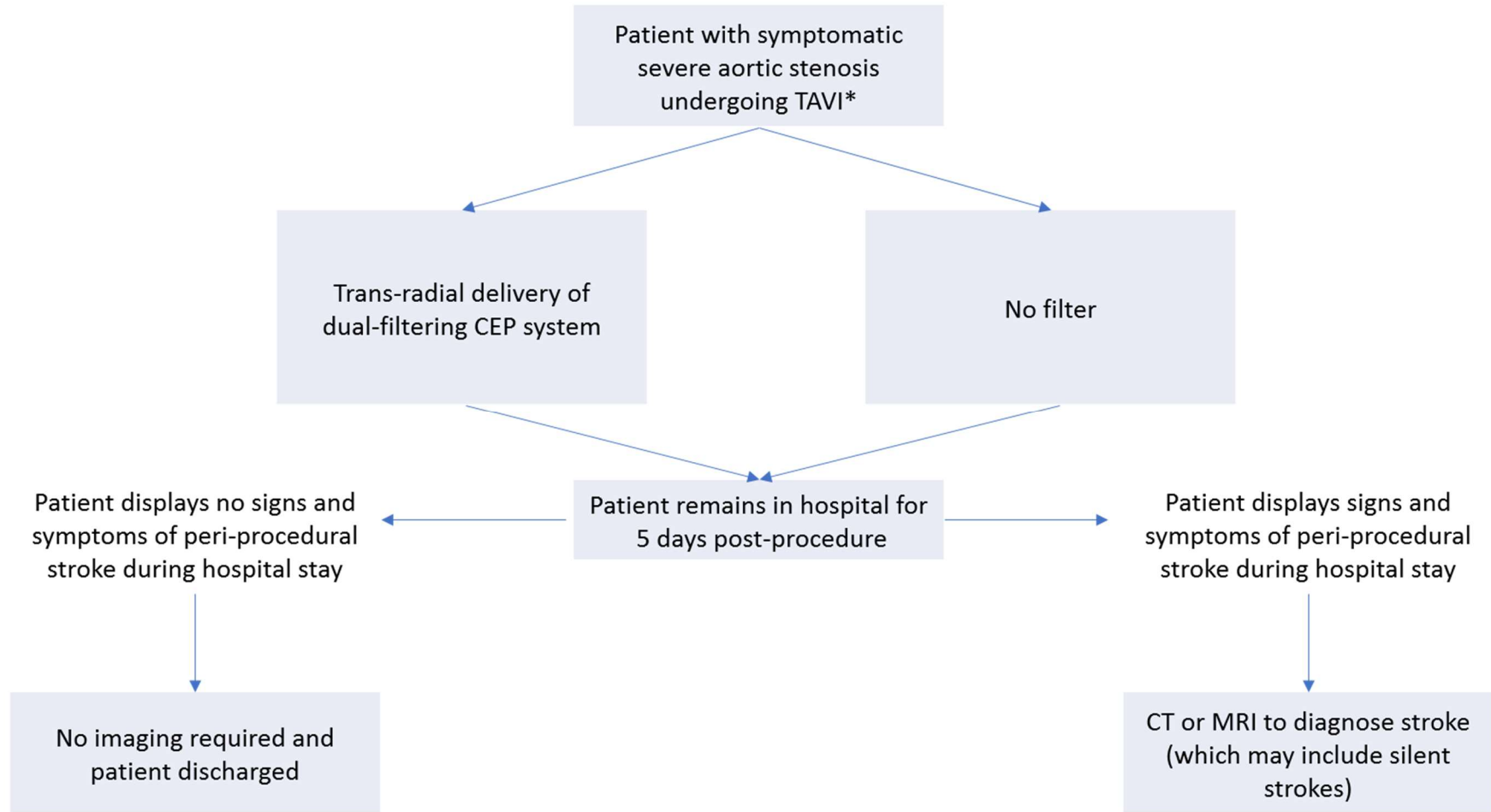


Figure 4 Clinical management algorithm

* Patients undergoing TAVI meeting the MBS eligibility criteria for TAVI procedure

Abbreviations: CEP, cerebral embolic protection; CT, computed tomography; MRI, magnetic resonance imaging; TAVI, transcatheter aortic valve implantation

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