



Australian Government

Department of Health

MSAC Application 1652

Transcatheter Aortic Valve Implantation via transfemoral delivery for patients at intermediate risk for surgery

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 name: Medtronic Australasia Pty Ltd

ABN: 47 001 162 661

Business trading name: Medtronic Australasia

Primary contact name:

REDACTED

Alternative contact name:

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?

N/A

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Transcatheter Aortic Valve Implantation (TAVI) via transfemoral delivery for patients at intermediate risk for surgery.

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)

Severe Aortic Stenosis (AS) is the abnormal narrowing of the aortic valve, which restricts the flow of blood from the left ventricle of the heart into the aorta. When the heart contracts to pump oxygenated blood from the left ventricle into the aorta, the aortic valve opens. If the aortic valve is narrowed, the heart no longer pumps blood efficiently and therefore, increases the blood pressure inside the left ventricle. In response to the extra workload, the muscle of the left ventricle thickens (concentric hypertrophy) and the chamber itself may eventually balloon out. Left untreated, congestive heart failure develops and death is likely.¹

This application is relevant to patients with severe, symptomatic AS classified as being at intermediate risk for surgery. ‘Intermediate risk’ is historically defined by a predicted 30-day risk of surgical mortality of 4-8%, based on the Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score.

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 TAVI procedure (relevant to this application) consists of the transfemoral insertion of a minimally invasive prosthetic heart valve that is positioned within the native aortic annulus. Once in situ, the valve is expanded while the heart is rapidly paced. The procedure is performed under fluoroscopic and transoesophageal guidance and under general anaesthesia or sedation and local anaesthetic.

The TAVI procedure can be performed using either a self-expandable, mechanically expandable or balloon-expandable device. Once the correct position is confirmed, the heart is again rapidly paced, the balloon or valve is expanded until the device meets native annular walls, and the guide wire, catheter and balloon (if present) are removed.

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

- Yes
 No

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

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

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

The existing MBS item number 38495 sufficiently describes the proposed service and is technology agnostic; this item includes the use of TAVI with balloon-expandable valves (BEV), self-expanding valves (SEV) or mechanically expanding valves (MEV).

The descriptor for MBS item number 38495 is: “TAVI, for the treatment of symptomatic severe aortic stenosis, performed via transfemoral delivery, unless transfemoral delivery is contraindicated or not feasible, in a TAVI

¹ <https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/aortic-stenosis>

Hospital on a TAVI Patient by a TAVI Practitioner – includes all intraoperative diagnostic imaging that the TAVI Practitioner performs upon the TAVI Patient”.

However, as per explanatory note TN.8.135, this MBS item is currently restricted to a TAVI Patient who “as a result of a TAVI Case Conference, has been assessed as having an unacceptably high risk for surgical aortic valve replacement and is recommended as being suitable to receive the service described in item 38495”.

The current proposal seeks to amend this explanatory note to also include patients at “intermediate risk for surgical aortic valve replacement”.

REDACTED

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

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

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

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

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

- Yes
- No

(g) If yes, please advise:

N/A

7. What is the type of service:

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

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

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

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

- Pharmaceutical / Biological
 Prosthesis or device
 No

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

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)?

N/A

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

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, some of the devices
 No, some are not included on the Prostheses List

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

Billing code(s): MI315

Product Sub Group: 08.17.01 - Transcatheter Aortic Valve Implantation

Trade name of prostheses: Medtronic CoreValve™ Evolut™ PRO transcatheter aortic valve

Description: Transcatheter aortic valve, self-expanding, re-sheath and/or complete recapture after partial deployment and redeployment

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

Billing code(s): MI259

Product Sub Group: 08.17.01 - Transcatheter Aortic Valve Implantation

Trade name of prostheses: Medtronic CoreValve™ Evolut™ R transcatheter aortic valve

Description: Transcatheter aortic valve, self-expanding, re-sheath and/or complete recapture after partial deployment and redeployment

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

Billing code(s): EL063

Product Sub Group: 08.17.01 - Transcatheter Aortic Valve Implantation

Trade name of prostheses: Edwards SAPIEN 3 Transcatheter Heart Valve

Description: Transcatheter, balloon expanded aortic heart valve with Commander Delivery System

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

Billing code(s): SJ394

Product Sub Group: 08.17.01 - Transcatheter Aortic Valve Implantation

Trade name of prostheses: (Abbott Medical) Portico transcatheter aortic valve

Description: Self-expanding transcatheter aortic tissue valve, nitinol stent, bovine valve

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

See Attachment A for further details. Note: Portico, LOTUS Edge, and ACURATE Neo are not yet TGA approved for intermediate risk, only high risk.

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

N/A

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

Yes

No

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

Edwards Lifesciences Pty Ltd: SAPIEN 3 device

Abbott Medical Australia Pty Ltd: Portico device

Boston Scientific Pty Ltd: LOTUS Edge

Boston Scientific Pty Ltd: ACURATE Neo

See Attachment A for further details. Note: Portico, LOTUS Edge, and ACURATE Neo are not yet TGA approved for intermediate risk, only high risk.

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

Single use consumables:

Angioplasty kit which includes drapes, manifolds and extensions tubing

Small and large bore vascular access sheaths

Lock syringes

3 way taps X 2

3 X bowls

2 X galley pots

Temporary pacing wire

Variety of pre-shaped catheters

Variety of standard or speciality wires

Multi-use consumables:

Temporary pacing cable

Temporary pacing box

Transthoracic or transoesophageal probe

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: Device

Product Name: Medtronic CoreValve™ Evolut™ PRO transcatheter aortic valve

Manufacturer's name: Medtronic Corevalve LLC, USA

Sponsor's name: Medtronic Australasia Pty Ltd

Type of therapeutic good: Device

Product Name: Medtronic CoreValve™ Evolut™ R transcatheter aortic valve

Manufacturer's name: Medtronic Corevalve LLC, USA

Sponsor's name: Medtronic Australasia Pty Ltd

Type of therapeutic good: Device

Product Name: Edwards SAPIEN 3 Transcatheter Heart Valve

Manufacturer's name: Edwards Lifesciences LLC, USA

Sponsor's name: Edwards Lifesciences Pty Ltd

Type of therapeutic good: Device

Product Name: Portico transcatheter aortic valve

Manufacturer's name: St Jude Medical, USA

Sponsor's name: Abbott Medical Australia Pty Ltd

Type of therapeutic good: Device

Product Name: LOTUS Edge transcatheter aortic valve

Manufacturer's name: Boston Scientific Corporation

Sponsor's name: Boston Scientific Pty Ltd

Type of therapeutic good: Device

Product Name: ACURATE Neo transcatheter aortic valve

Manufacturer's name: Boston Scientific Corporation

Sponsor's name: Boston Scientific Pty Ltd

See Attachment A for further details. Note: Portico, LOTUS Edge, and ACURATE Neo are not yet TGA approved for intermediate risk, only high risk.

- (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

See Attachment A for details. Note that TAVI devices from:

- Medtronic Australasia (CoreValve™ Evolut™ R and Evolut™ PRO) are TGA-approved for patients with Aortic Stenosis at all surgical risk levels (low – high surgical risk)
- Edwards Lifesciences (SAPIEN3) are TGA-approved for patients with Aortic Stenosis at all surgical risk levels (low - high surgical risk).
- Abbott Medical Australia (Portico) is only TGA-approved for patients with Aortic Stenosis who are considered high surgical risk. It is unknown whether there is an application underway/being assessed for patients who are considered low or intermediate risk.
- Boston Scientific Corporation (LOTUS Edge and ACURATE Neo) is only TGA-approved for patients with Aortic Stenosis who are considered high surgical risk. It is unknown whether there is an application underway/being assessed for patients who are considered low or intermediate risk.

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

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?

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 | Date of publication |
|----|-----------------------------|--|---|---|------------------------------|
| 1. | Randomised Controlled Trial | Leon 2016 , 'Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients', <i>NEJM</i> , 374 (17): pp. 2252-62. | <u>PARTNER 2A</u> RCT of 2032 intermediate-risk patients with severe AS at 57 centres who underwent either TAVI or SAVR. Of patients undergoing TAVI, 76.3% were treated using the transfemoral approach. Primary endpoint was a composite of all-cause mortality or disabling stroke at 2 years. Results are also reported for all-cause mortality, disabling or any stroke, TIA, rehospitalisation, MI, MVC, LT or disabling bleeding, AKI, new AF, new PP, endocarditis, AVR and coronary obstruction. | https://pubmed.ncbi.nlm.nih.gov/27040324/ | Apr 2016 |
| 2. | Randomised Controlled Trial | Makkar 2020 , 'Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement', <i>NEJM</i> , 382 (9), pp. 799-809. | | https://pubmed.ncbi.nlm.nih.gov/31995682/ | Feb 2020 (5-year results) |
| 3. | Randomised Controlled Trial | Reardon 2017 , 'Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients', <i>NEJM</i> , 376 (14), pp. 1321-1331. | <u>SURTAVI</u> RCT of 1660 patients considered to be at 'intermediate risk' with severe AS at 87 centres who underwent either TAVI or SAVR. Of patients undergoing TAVI, 93.6% were treated using the transfemoral approach. Primary endpoint was a composite of all-cause mortality or disabling stroke at 2 years. Results are also reported for all-cause and CV or VR mortality, AVR, disabling or any stroke, TIA, MI and hospitalisation. Reported results for the strata with an STS score of 3-5% or ≥5% are most relevant to this application. | https://pubmed.ncbi.nlm.nih.gov/28304219/ | Mar 2017 |

AF, atrial fibrillation; AKI, acute kidney injury; AS, aortic stenosis; AVR, aortic valve reintervention; CV, cardiovascular; IR, intermediate risk; LT, life-threatening; MVC, major vascular complication; MI, myocardial infarction; PP, permanent pacemaker; RCT, randomised clinical trial; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; TAVI, transcatheter aortic valve implantation; TIA, transient ischaemic attack; VR, valve related.

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.

None identified

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):

REDACTED

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

REDACTED

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

None

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

Edwards Lifesciences

Abbott Medical

Boston Scientific

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

Name of expert 1: REDACTED

Telephone number(s): REDACTED

Email address: REDACTED

Justification of expertise: REDACTED

Name of expert 2: REDACTED

Telephone number(s): REDACTED

Email address: REDACTED

Justification of expertise: REDACTED

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

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

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

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

Severe Aortic Stenosis (AS) is the abnormal narrowing of the aortic valve, which restricts the flow of blood from the left ventricle of the heart into the aorta. When the heart contracts to pump oxygenated blood from the left ventricle into the aorta, the aortic valve opens. If the aortic valve is narrowed, the heart no longer pumps blood efficiently and therefore, increases the blood pressure inside the left ventricle. In response to the extra workload, the muscle of the left ventricle thickens (concentric hypertrophy) and the chamber itself may eventually balloon out. Some of the causes of aortic stenosis include congenital valve abnormalities, rheumatic heart disease and calcium deposits (the most common cause of aortic stenosis in people aged 70 years and over).²

Aortic stenosis may be asymptomatic for many years. Symptoms may appear later in life after decades of gradual progressive narrowing of the aortic valve. The onset of symptoms may be gradual or abrupt and may include breathlessness, coughing at night when lying down, fainting, heart palpitations, pains in the chest (angina), fatigue and visual problems.³

Aortic stenosis can be a serious and potentially life-threatening condition with complications including pulmonary oedema (fluid in the lungs), cardiomegaly (enlarged heart), heart failure and heart arrhythmia.⁴ People with severe AS are at 38%, 32% and 18% risk of dying at one, five and ten years respectively.⁵ This risk increases to 50% and 80% at two and five years respectively for patients without receiving an aortic valve replacement.⁶

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:

The mean age of Australian patients undergoing SAVR and TAVI for the year 2019 is 70 and 81 years of age respectively (as shown in Table 1 based MBS item statistics).

Table 1. MBS service volumes for SAVR and TAVI by age group, 2019, Australia

| Age range | MBS item 38488 SAVR | MBS item 38489 SAVR | SAVR total | MBS item 38495 TAVI |
|-----------|---------------------|---------------------|------------|---------------------|
| 0-4 | 2 | 0 | 2 | 0 |
| 5-14 | 5 | 2 | 7 | 0 |
| 15-24 | 6 | 8 | 14 | 0 |
| 25-34 | 8 | 11 | 19 | 0 |

² <https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/aortic-stenosis>

³ *Ibid.*

⁴ Nishamura, R.A., et al, 2014, '2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease: Executive Summary', *JACC*, vol. 63, no. 22, pp. 2440-2492

⁵ Varadarajan, P. et al, 2006, 'Clinical profile and natural history of 453 nonsurgically managed patients with severe aortic stenosis', *Ann Thorac Surg*, vol. 82, no. 6, pp. 2111-5

⁶ Otto, C.M. 2000, 'Timing of aortic valve surgery', *Heart*, vol. 84, pp. 211-8.

| | | | | |
|-----------------|-----------|-----------|-----------|-----------|
| 35-44 | 40 | 9 | 49 | 0 |
| 45-54 | 117 | 9 | 126 | 5 |
| 55-64 | 327 | 5 | 332 | 15 |
| 65-74 | 959 | 7 | 966 | 127 |
| 75-84 | 934 | 3 | 937 | 698 |
| >=85 | 104 | 1 | 105 | 658 |
| Unknown | 0 | 0 | 0 | 0 |
| Total | 2502 | 55 | 2557 | 1503 |
| Mean age | 71 | 44 | 70 | 81 |

SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; MBS, Medicare Benefits Schedule;

Source: http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp

Patients with severe AS usually present to their general practitioner (GP), before being referred to a cardiologist for investigations including physical examination such as listening to the heart with a stethoscope, chest x-ray, electrocardiogram (ECG), echocardiogram, cardiac catheterisation, coronary angiogram to assess whether there is coronary artery disease in addition to the recognised aortic valve disease and cardiac magnetic resonance imaging (MRI). Valvular regurgitation and functional status (by the New York Heart Association (NYHA) functional class system) is also assessed.

Assessment of surgical risk is determined by a multi-disciplinary heart team via attendance at a case conference. This application pertains to patients who are determined to be at intermediate risk of surgery by a heart team.⁷

Intermediate risk is generally defined by predicted risk of surgical mortality of 4-8% at 30 days, based on the STS-PROM score. However, the Ratified PICO Confirmation for MSAC Application 1552 states that a patient be defined at intermediate risk of surgery if they meet the criteria below:

- No more than mild frailty; AND
 - STS-PROM 4-8%; OR
 - One major organ system compromise not to be improved post-operatively; OR
 - Possible procedure-specific impediment

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):

See Attachment B for a flowchart depicting the current clinical management algorithm.

REDACTED

As described in Q25 above, patients will usually present to a GP who will order the initial investigations and refer the patient to a cardiologist. There are three treatment options for severe AS being medical management, SAVR or TAVI. Medical management consists of pharmacologic treatment to alleviate symptoms and, in certain cases, balloon aortic valvuloplasty (BAV) to enlarge the aortic valve opening. Balloon valvuloplasty does not cure the condition and further surgical treatment may be needed later in life. This procedure is usually used as a temporary measure or to relieve symptoms when other options are not available.

⁷ Kodali, S. et al, 2016, 'Early clinical and echocardiographic outcomes after SAPIEN 3 transcatheter aortic valve replacement inoperable, high-risk and intermediate-risk patients with aortic stenosis', *Eur Heart Journ*, vol. 37, pp.2252-2262.

PART 6b – INFORMATION ABOUT THE INTERVENTION

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

For TAVI delivered via the transfemoral route delivery (relevant to this application), the patient may only require local anaesthesia and sedation, however general anaesthesia is an option. The procedure is performed without cardio-pulmonary bypass and under the guidance of fluoroscopy, transoesophageal echocardiography (TOE) and/or aortography.⁸

A sheath is inserted into the femoral artery to permit access for the TAVI device into the peripheral arterial system. The aortic valve is often predilated via balloon valvuloplasty during rapid ventricular pacing. Device implantation is then carried out under rapid pacing again and expanding the valve until the device meets the native annular walls.⁹ The MEV design has a unique mechanical deployment mechanism whereby significant radial force is generated and the valve is fixed in place by the engagement of a locking mechanism.¹⁰ The SEV and MEV design allows for recapture and repositionability prior to final release, as opposed to BEV technology where no repositioning is possible. The femoral sheath is removed and the artery is closed using a pre-closure device.^{11,12}

Aortography and transthoracic echocardiography are then performed to assess the location and the degree of any aortic regurgitation, and the functioning of the coronary arteries. Modern day care following TAVI is minimalist, with most patients returning from the procedure suite (to either a coronary care, high dependency or intensive care unit) with little more than an intravenous cannula and cardiac telemetry.¹³

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

Medtronic Australasia currently has two TAVI devices: CoreValve™ Evolut™ R transcatheter aortic valve and CoreValve™ Evolut™ PRO transcatheter aortic valve. There are other TAVI valves available in Australia including SAPIEN 3 (Edwards Lifesciences), Portico (Abbott Medical Australia), ACURATE Neo and LOTUS Edge (Boston Scientific).

Currently, there are three valve designs for TAVI catheters, self-expandable, balloon-expandable and mechanical expandable valves. The SAPIEN 3 device (Edwards Lifesciences) is balloon expandable, LOTUS Edge is mechanically expandable, and Evolut R, Evolut PRO, Portico and ACURATE Neo (Boston Scientific) are self expandable valves, each with different designs.

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?

Currently, TAVI is included on the MBS for patients with symptomatic severe AS who are at *high* risk of surgery or who are inoperable. TAVI is a new approach in Australia for treating patients who have symptomatic severe aortic stenosis and are at *intermediate* risk for surgery.

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 lifespan of a TAVI valve is expected to be similar to that of a Surgical Aortic Valve Prosthesis.

⁸ Kronzon, I. et al, 2015, 'Optimal Imaging for Guiding TAVR: Transesophageal or Transthoracic Echocardiography, or Just Fluoroscopy?', *JACC*, vol. 8, no. 3, pp. 361-370.

⁹ Nelson, A. et al, 2018, 'Transcatheter aortic valve implantation: a new standard of care', *MJA*, vol. 209, no. 3, pp. 136-141.

¹⁰ Fanning, J. et al, 2013, 'Transcatheter aortic valve implantation (TAVI): Valve design and evolution', *International Journal of Cardiology*, 168(3), pp. 1822–1831.

¹¹ *Ibid.*

¹² Nelson *op. cit.*

¹³ *Ibid.*

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:

No other healthcare resources or medical services would need to be delivered at the same time as the TAVI procedure.

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

Interventional cardiologist or a cardiothoracic surgeon (must be an accredited TAVI practitioner)

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

The TAVI procedure cannot be delegated.

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

MBS funding is only available for an interventional cardiologist or a cardiothoracic surgeon (must be an accredited TAVI practitioner).

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 following training and qualifications are required for the TAVI specialists: ¹⁴

- Cardiothoracic surgeons
 - Cardiothoracic Surgery Program
 - Eligibility to be a Fellow of the Royal Australasian College of Surgeons or otherwise qualified to practice cardiothoracic surgery in Australia
 - Accredited TAVI Practitioner (accreditation is conducted by the Accreditation Committee appointed by Cardiac Accreditation Services Limited).
- Interventional Cardiologists
 - Advanced Training Curriculum in Cardiology
 - Eligibility to be a Fellow of the Royal Australasian College of Physicians or otherwise qualified to practice interventional cardiology in Australia
 - Accredited TAVI Practitioner (accreditation is conducted by the Accreditation Committee appointed by Cardiac Accreditation Services Limited).

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

¹⁴ <http://tavi.org.au/>

The public or private hospital must be deemed as being 'clinically acceptable' to performing the TAVI procedure (MBS Item # 38495).¹⁵

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

The procedure setting includes public and private hospital, however the hospital must be deemed as being 'clinically acceptable' to performing the TAVI procedure (MBS Item # 38495).

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):

SAVR is the comparator - an open-heart surgical procedure to repair or remove the narrowed aortic valve and replace it with a bioprosthesis or mechanical aortic valve. No other healthcare resources are expected with TAVI at the same time as the SAVR procedure.

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

MBS Item # 38488

VALVE REPLACEMENT with BIOPROSTHESIS OR MECHANICAL PROSTHESIS

Fee: \$1,969.25

MBS Item # 38489

VALVE REPLACEMENT with allograft (subcoronary or cylindrical implant), or unstented xenograft

Fee: \$2,342.00

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):

REDACTED

Following SAVR, patients receive an echocardiogram at one, six and 12 months and may also require treatment/follow-up for complications (stroke, heart failure, permanent pacemaker implantation and other cardiovascular events).

¹⁵

[http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/7F459C457DBE500ECA2581C5001C0773/\\$File/Factsheet%20-%20TAVI.pdf](http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/7F459C457DBE500ECA2581C5001C0773/$File/Factsheet%20-%20TAVI.pdf)

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:

It is estimated that 80% of intermediate risk patients may access TAVI if it was available via the MBS (see Q49 and Q50 for further information).

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):

Patients undergoing SAVR require a longer hospital stay (in intensive care and standard wards) and recovery time, compared to patients undergoing TAVI, as it is an open-chest surgery.

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):

TAVI is non-inferior to SAVR in patients with symptomatic severe AS and at intermediate risk of surgery in terms of overall survival and the incidence of disabling stroke. TAVI also has similar safety (adverse event rates) compared with SAVR.

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:

Bleeding events (life-threatening, disabling, major)

Major vascular complications

Myocardial infarction

Valve endocarditis

Clinical Effectiveness Outcomes:

Overall survival

Disabling stroke

All stroke

Quality of life

Healthcare resources:

Cost of valvular prosthesis

Cost associated with changes in clinical management:

Testing required before the procedure

Procedural length of stay

Post-discharge rehabilitation

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

The prevalence of AS is age-dependent. A large population-based study from the National Health, Lung, and Blood Institute in the United States estimated the prevalence of moderate or severe AS to range from 0.02% in persons aged 18-44 years to 2.8% in persons aged over 75 years. Similar trends are present in other economically developed nations.¹⁶

Osnabrugge et al (2013) estimated that across several countries (Switzerland, Finland, the Netherlands, Belgium, United States (US) and Taiwan): 3.4% of the population over 75 years have severe AS; of those, 75.6% would be symptomatic; of those, 15.8% are at intermediate risk of surgery.¹⁷ Thourani et al conducted a retrospective study of 141,905 US patients and estimated that 13.9% of patients who underwent SAVR were of intermediate risk.¹⁸

Based on the epidemiological data from Osnabrugge (2013), the prevalence of severe symptomatic AS in Australia in 2020 is 107,539, of which 16,991 patients would be considered to be an intermediate risk for surgery.

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

It is anticipated that this will be a once in a lifetime treatment.

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

Advice from a KOL is that they have been implanting CoreValve for 12 years and have not had a patient need a replacement. This would suggest Corevalve/Evolut TAVI to have a lifespan of 10-15 years +.

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

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The number of SAVR procedures claimed under the MBS is used to estimate the number of patients who would be eligible for the proposed TAVI service. In 2019, MBS Item 38488 was claimed 2,502 times and MBS Item 38489 was claimed 55 times (2,557 SAVR procedures in total).

Given that the mean age of patients undergoing SAVR in Australia is 71 years, the following estimates are made using the utilisation of MBS item numbers 38488 and 38489 as a proportion of the population over 65.

¹⁶ Thaden, J.J. et al, 2014, 'The Global Burden of Aortic Stenosis', *Prog. Cardiovasc. Dis*, vol. 56, no. 6, pp. 565-571

¹⁷ Osnabrugge, M.S. et al, 2013, 'Aortic Stenosis in the Elderly. Disease Prevalence and Number of Candidates for Transcatheter Aortic Valve Replacement: A Meta-Analysis and Modelling Study', *JACC*, vol. 62, no. 11, pp. 1002-1012.

¹⁸ Thourani, V.H. et al, 2015, 'Contemporary real-world outcomes of surgical aortic valve replacement in 141,905 low-risk, intermediate-risk, and high-risk patients', *Ann Thorac Surg*, vol. 99, pp. 55-61.

| | | 2019 | 2020 | 2021 |
|---|--|-----------|-----------|-----------|
| A | Australian population over 65 years of age | 4,053,834 | 4,183,738 | 4,318,848 |
| B | SAVR (MBS items 38488 and 38489) | 2,557 | 2,639 | 2,724 |
| C | Intermediate Risk Group (15.8% of B) | 404 | 417 | 430 |

MBS, Medicare Benefits Schedule; SAVR, surgical aortic valve replacement

Source: Population figures sourced from ABS population projections, Australia (Series B). MBS item volumes sourced from Medicare statistics online (accessed 7 July 2020). SAVR volumes calculated for years 2020 – 2021 as a proportion of the population over 65 from the year 2019. i.e. The eligible population in each year is assumed to increase by an equivalent factor to the projected population aged 65 years and older (i.e., the underlying prevalence rates of severe symptomatic AS and intermediate surgical risk are not assumed to change over time).

It is estimated that 430 patients would be eligible for the proposed TAVI service in 2021. It is however, unlikely that all these patients would access TAVI since some patients may be referred to a cardiologist or surgeon who is not part of a TAVI Heart Team and therefore not refer the patient to receive TAVI.

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:

Osnabrugge et al 2013 estimated that 80% of high risk/inoperable patients eligible for TAVI received the procedure. Therefore, an uptake rate of 80% is assumed for intermediate risk patients who are eligible assuming that capacity is available to meet demand. Demand is expected to increase on hospitals with accredited TAVI practitioners. Leakage to populations not specific to this application is unlikely given that eligibility to TAVI is determined by a TAVI Heart Team (see Attachment A for clinical management algorithm).

The eligible population in each year is assumed to increase by an equivalent factor to the projected population aged 65 years and older (i.e., the underlying prevalence rates of severe symptomatic AS and intermediate surgical risk are not assumed to change over time).

| | | 2021 | 2022 | 2023 |
|---|--|-----------|-----------|-----------|
| A | Australian population over 65 years of age | 4,318,848 | 4,454,687 | 4,593,986 |
| B | Eligible population | 430 | 444 | 458 |
| C | Uptake rate (patients accessing TAVI 80% X B)^ | 344 | 355 | 366 |

MBS, Medicare Benefits Schedule; TAVI, transcatheter aortic valve implantation.

^ Osnabrugge et al 2013 estimated that 80% of high risk/inoperable patients eligible for TAVI received the procedure. Therefore, an uptake rate of 80% is applied for intermediate risk patients who are eligible.

Source: Population figures sourced from ABS population projections, Australia (Series B). MBS item volumes sourced from Medicare statistics online (accessed 7 July 2020). SAVR volumes calculated for years 2020 – 2023 as a proportion of the population over 65 from the year 2019.

PART 8 – COST INFORMATION

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

The estimated MBS costs of the TAVI procedure are provided below. Note that TAVI implants are currently included on the Prostheses List at a list price of \$22,932.

| Cost Item | MBS Item Number | 100% MBS Fee | 75% Benefit |
|--|-----------------|--------------|-------------|
| TAVI Case Conference -Organiser | 6080 | \$52.50 | \$39.40 |
| TAVI Case Conference Attendance X 3 | 6081 | \$39.15 | \$29.40 |
| TAVI Procedure including all intraoperative diagnostic imaging | 38495 | \$1,476.95 | \$1,107.75 |
| Assistant* | 51303 | \$295.39 | \$221.55 |
| Initiation of Anaesthesia | 21941 | \$142.80 | \$107.10 |
| Anaesthesia Time Units 1:31 to 1:45 hours | 23075 | \$142.80 | \$107.10 |
| ICU Attendance | 13870 | \$373.40 | \$280.05 |
| Transthoracic echocardiography | 55113 | \$234.10 | \$175.60 |

*costs calculated from 20% of the established fee of the TAVI procedure (MBS item 38495 \$1,476.95).

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

The procedure will typically take 1 – 1.5 hours.

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.

The existing MBS item number 38495 adequately describes the proposed service and is technology agnostic; this item includes the use of TAVI with all valve types. However, as per explanatory note TN.8.135, this MBS item is currently restricted to a TAVI Patient who “as a result of a TAVI Case Conference, has been assessed as having an unacceptably high risk for surgical aortic valve replacement and is recommended as being suitable to receive the service described in item 38495”.

This application proposes to revise the explanatory note to also include patients at “intermediate risk for surgical aortic valve replacement”.

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| Category 3 – Therapeutic Procedures – Surgical Operations |
| Proposed item descriptor: 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 |
| Fee: \$1,476.95 |