Australian Government

Department of Health

Application Form

(New and Amended

Requests for Public Funding)

(Version 2.4)

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

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

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

Phone: +61 2 6289 7550
Fax: +61 2 6289 5540
Email: hta@health.gov.au
Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant): Edwards Lifesciences Pty Ltd
Corporation name:
ABN:
Business trading name:

Primary contact name:

Business:
Mobile:
Email:

Alternative contact name:

Alternative contact numbers
Business:
Mobile:
Email:

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

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 a narrowing of the aortic valve restricting the flow. Aortic stenosis is often caused by a build-up of calcium on the valve leaflets, causing them to become stiff and reducing their ability to open and close efficiently. AS is associated with high pressure inside the left ventricle and as a result of the excessive workload, the muscle of the left ventricle hypertrophies. This results in inefficient pumping of blood throughout the body. Left untreated, congestive heart failure develops and death is likely.

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 is a transfemoral percutaneous minimally invasive insertion of a 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 transosophageal guidance and under general anaesthesia or local anaesthetic.

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)

The existing MBS item number 38495 adequately describes the proposed service. At the time of implementation of this item number, TGA approval of an intermediate risk for surgery indication was not available. Therefore, the existing item number would suffice.

(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:

Insert relevant MBS item numbers here

(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):

Insert description of 'other' amendment here

(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:

Insert description of other public funding mechanism here

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?

Not applicable

☐ Yes
☐ No

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

Not applicable

Insert PBS item code(s) here

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

Not applicable

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

Insert PBAC submission item number here

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

Not Applicable

Trade name: Insert trade name here
Generic name: Insert generic name here

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

☒ Yes
☐ NoIf yes, please provide the following information (where relevant):
Billing code(s): EL063
Trade name of prostheses: Edwards SAPIEN 3 Transcatheter Heart Valve
Clinical name of prostheses: Transcatheter, balloon expanded aortic heart valve with Commander Delivery System

Other device components delivered as part of the service: The Prostheses Listing includes the valve and delivery system..

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

Not Applicable

☐ Yes
☐ No

(c) 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

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

St Jude Medical Australia Pty Ltd

Medtronic Australasia Pty Ltd

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.
Sheaths,
Lock syringes
3 way taps X 2
3 X bowls
2 X Galley pot
Temporary pacing wire
Variety of pre-shaped catheters
Variety of 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: Transfemoral – Aortic transcatheter heart valve bioprosthesis, stent-like framework
Manufacturer's name: Edwards Lifesciences LLC
Sponsor's name: Edwards Lifesciences Pty Ltd

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

☒ Class III
☐ AIMD
☐ N/A

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

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

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

☒ Yes (if yes, please provide details below)
☐ No

ARTG listing, registration or inclusion number: 284496

TGA approved indication(s), if applicable: The Edwards SAPIEN 3 THV, Edwards Commander delivery system and accessories are indicated for use in patients with severe, symptomatic, calcific aortic valve stenosis with an STS-PROM of 8 or Logistic EuroSCORE > 15

TGA approved purpose(s), if applicable: As above

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

There is an application with the TGA to extend the approved indication to include patients who are at intermediate risk for surgery

Date of submission to TGA: 23rd May 2017
Estimated date by which TGA approval can be expected: 15th August 2018
TGA Application ID: DC-2017-02153-1
TGA approved indication(s), if applicable: The Edwards SAPIEN 3 valve, Edwards Commander delivery system and accessories are indicated for use in patients with severe, symptomatic, calcific aortic valve stenosis who are judged by a Heart Team, to be at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 3% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).

TGA approved purpose(s), if applicable: If applicable, insert description of TGA approved purpose(s) here

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?

Not applicable

☐ Yes (please provide details below)
☒ No

Estimated date of submission to TGA: Insert date of submission here
Proposed indication(s), if applicable: If applicable, insert description of proposed indication(s)
Proposed purpose(s), if applicable: If applicable, insert description of proposed purpose(s) here

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.	**Propensity Score Analysis**	**Thourani VH et al *'Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: propensity score analysis'* Lancet 2016 387 (10034): p.2218-25**	**The results of an observational study of 1077 intermediate risk patients at 51 sites receiving TAVI were compared with an historical cohort of intermediate risk patients receiving SAVR using propensity score analysis**	**https://www.ncbi.nlm.nih.gov/pubmed/27053442**	**May 2016**
2.	Randomised Controlled Trial	**Leon MB et al *'Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients'* NEJM 2016, 374 (17): p. 2252-62**	**Randomised Controlled Trial of 2032 intermediate-risk patients with severe aortic stenosis at 57 centres who underwent either TAVR or SAVR. Primary endpoint was death from any cause or disabling stroke at 2 years. Please note that reported results for the transfemoral cohort are most relevant to this application.**	**https://www.nejm.org/doi/full/10.1056/NEJMoa1514616**	April 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***
3.	**Multi-centre non-randomised registry**	**Kodali S et al *'Early clinical and echocardiographic outcomes after SAPIEN 3 transcatheter aortic valve replacement in inoperable, high-risk and intermediate-risk patients with aortic stenosis'* Eur Heart J, 2016**	**Patients with severe, symptomatic AS (high surgical risk or inoperable N=583, Intermediate risk N=1078) were enrolled in a non-randomised registry at 57 sites in the USA and Canada and received TAVR with SAPIEN 3**	https://www.ncbi.nlm.nih.gov/pubmed/27190101	**July 2016**
4.	**Randomised Controlled Trial**	Baron SJ *'Health Status Benfits of Transcatheter vs Surgical Aortic Valve Replacement in Patients with Severe Aortic Stenosis at Intermediate Surgical Risk'* JAMA Cardiol. 2017;2 (8):837-845	**Randomised Controlled Trial of 2032 intermediate-risk patients with severe aortic stenosis at 57 centres who underwent either TAVR or SAVR. Health related quality of life was assessed at baseline, 1 month, 1 year and 2 years. Note, reported results for the transfemoral cohort are most relevant to this application.**	**https://jamanetwork.com/journals/jamacardiology/article-abstract/2635358**	**August 2017**

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
5.	**Propensity score analysis**	Baron, S. J., et al. (2018). "Effect of SAPIEN 3 Transcatheter Valve Implantation on Health Status in Patients With Severe Aortic Stenosis at Intermediate Surgical Risk: Results From the PARTNER S3i Trial." JACC Cardiovasc Interv **11**(12): 1188-1198.	1,078 patients at intermediate surgical risk were treated with SAPIEN 3 TAVR in the PARTNER S3i trial. Based on the KCCQ instrument, S3 resulted in improved QOL at both 1 month and 1 year compared with both SAVR and XT-TAVR	https://www.ncbi.nlm.nih.gov/pubmed/29860075	**June 2018**
6.	**Retrospective**	Coylewright, M., et al., Patient-defined goals for the treatment of severe aortic stenosis: a qualitative analysis. Health Expect, 2016. 19(5): p. 1036-43.	Out of 100 severe aortic stenosis (AS) patients treated with TAVI, 93% of patients have a quality of life treatment goal, including ability to do activity and maintaining independence.	https://www.ncbi.nlm.nih.gov/pubmed/26275070	**October 2016**
7.					

** 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.	**Single Arm multi-centre registry**	**SOLACE AU Trial** (NCT01675596)	**Single arm open label clinical trial of 200 patients at 11 clinical sites within Australia. Safety and efficacy is to be evaluated at baseline, discharge, 30 days, 6 months and 1-5 years**	**https://www.heartlungcirc.org/article/S1443-9506(16)30730-2/pdf**	**TBC**
	Cost effectiveness analysis	Cohen, D., Cost-effectiveness of transcatheter vs. surgical aortiv valve replacement in intermediate risk patients. Results from the PARTNER 2A and SAPIEN 3 intermediate risk trials. Presented at TCT. October 31, 2017. Denver, CO. 2017.	The index hospitalization costs (excluding MD fees) were lower for TAVR with SAPIEN 3 than SAVR in intermediate-risk patients ($52,035 vs. $53,796). Substantially lower follow-up costs were reported for SAPIEN XT and SAPIEN 3 compared to surgery (-$9,304 and -$11,377, respectively p<0.001).	**https://www.acc.org/~/media/Clinical/PDF-Files/Approved-PDFs/2017/10/24/TCT17_Presentation_Slides/Tue_Oct31/PARTNER-2A-SAPIEN-3-Cost-Effectiveness-TCT-2017.pdf**	**October 2017**

** 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):**

    Cardiac Society of Australis and New Zealand (CSANZ)

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

    Australian and New Zealand Society of Cardiac and Thoracic Surgeons

    Cardiac Society of Australia and New Zealand (CSANZ)

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

Heart Foundation & Consumer Health Forum

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

    Medtronic Australasia Pty Ltd

    Abbott

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:

    Telephone number(s):

    Email address:

    Justification of expertise:

    Name of expert 2:

    Telephone number(s):

    Email address:

    Justification of expertise:

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

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

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

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

Aortic stenosis (AS) is one of the most common and most serious valve disease problems. AS is a narrowing of the aortic valve opening. AS restricts the blood flow from the left ventricle to the aorta and may also affect the pressure in the left atrium. Although some people have AS due to a congenital heart defect (bicuspid aortic valve) this condition more commonly develops during aging as calcium and/or scarring damages the valve and restricts the flow rate of blood through the valve. AS is not merely a result of aging but is a process of inflammation, lipid accumulation and calcification characterised by subendothelial thickening[1]

AS results in structural changes to the heart from increased load on the left ventricle (LV) and hypertrophy (or enlargement of the heart). Stenotic valves may not close fully resulting in regurgitation back into the left ventricle. AS is a progressive disease that is asymptomatic until the latest stages of the disease. Symptomatic severe AS is classified as Stage D AS and can be confirmed by the presence of symptoms (eg, dyspnea, angina, syncope, heart failure), severely calcified valve leaflets with reduced opening, jet velocity (V_{max}) ≥4 m/s, and mean gradient ≥40 mm Hg. Variations in valve haemodynamics and the presence of symptoms are used to further subclassify symptomatic severe AS.[2] AS becomes symptomatic at the most severe stage of the disease. Symptoms include exertional dyspnoea or decreased exercise tolerance, exertional angina or exertional syncope or presyncope. Left untreated patients will experience heart failure and angina.[2] Patients are then at high risk for sudden death. Prognosis is poor once there is a mean aortic valve gradient greater than 40mmhg. Severe AS is associated with high death rates of 38%, 32% and 18% at 1 year, 5 years and 10 years respectively[3]. In the absence of aortic valve replacement (AVR), the survival of these patients can be as low as 50% at two years and 20% at five years.[4]

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

Patients with severe AS are typically elderly, although younger adults may present with a congenital malformation of the valve. Patients may present to either a general practitioner (GP) or alternatively an unexplained episode of shortness of breath, angina or syncope may trigger a presentation to an emergency room. Regardless of presentation an echocardiograph is the investigation to confirm the diagnosis of AS. Echocardiographic criteria for the definition of severe AS are as follows.[5]

Valve area (cm^2)	**<1.0**
Indexed valve area (cm^2/m^2BSA)	**<0.6**

[1] Thaden J.J. et al *'The Global Burden of Aortic Stenosis'* Prog. CardVasc. Dis 56 (2014) 565-571
[2] Nishamura R A., et al *'2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease: Executive Summary.' JACC Vol 63, Iss 22, 2014*
[3] Varadarajan P et al *'Clinical profile and natural history of 453 nonsurgically managed patients with severe aortic stenosis'* Ann Thorac Surg. 2006 Dec; 82(6):2111-5
[4] Otto CM. Timing of aortic valve surgery. *Heart*. 2000;84:211-8.
[5] Andeotti F et al *'Guidelines on the management of valvular heart disease (version 2012): The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESD) and the European Association for Cardio-Thoracic Surgery (EACTS)* Eur Heart Journ Vol 33, Iss 19, 1 Oct 2012

Valve area (cm²)	**<1.0**
Mean gradient (mmhg)	**>4.0**
Maximum jet velocity (m/s)	**>4.0**
Velocity ratio	**<0.25**

Transoesophageal echocardiography may also be considered. Other tests that may be conducted include cardiac MRI, exercise echocardiography, multi-slice computed tomography and coronary angiography. Valvular regurgitation is also assessed. Functional status is assessed by the New York Heart Association functional class system.

Assessment of surgical risk is determined by either a multi-disciplinary heart team. This application pertains to patients who are determined to be at intermediate risk of surgery. by a heart team[6]

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):

Patients usually present to a GP who will order the initial investigations as described in Question 25. Three treatment options are available to target these goals: medical management, surgical aortic valve replacement (SAVR), and TAVR. Medical management consists of pharmacologic treatment to alleviate symptoms and, in certain cases, balloon aortic valvuloplasty (BAV) to enlarge the aortic valve opening. However, these treatments have not been found to provide sustained symptom relief, alter the disease course, or improve survival in patients with severe symptomatic AS. Medical management is not usually first line therapy for an operable patient so a referral is made to either a cardiologist or to a cardiothoracic surgeon. Referral is then made to a TAVI Heart Team to determine the patient's suitability for the TAVI procedure

PART 6b – INFORMATION ABOUT THE INTERVENTION

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

In Australia TAVI is performed in a cardiac catheterisation or an operating room. TAVI is generally performed under general or local anaesthesia and sedation, but for transfemoral delivery which this application is concerned with, sedation and analgesia may be sufficient. The procedure is performed without cardio-pulmonary bypass.

The procedure is performed under the guidance of fluoroscopy and transoesophageal echocardiography (TOE), however this is not always necessary in an intermediate risk patient. Aortography may also be used. A percutaneous sheath is inserted into the femoral artery with a guide wire that crosses the aortic valve. The aortic valve is predilated via balloon valvuloplasty while the heart is rapidly paced. The valve is provided mounted on a balloon catheter. It is inserted percutaneously over the guidewire until it crosses the aortic valve. Optimum positioning is confirmed by fluoroscopy. Once the correct position is confirmed, the heart is again rapidly paced, the balloon is expanded until the device meets the native annular walls. The balloon is deflated and the catheter and guidewire are removed.

[6] Kodali S et al *'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 doi:10.1093/eurheartj/ehw112

Immediately following the procedure, aortography and transthoracic echocardiography are again performed to assess the location and the degree of any aortic regurgitation, and the functioning of the coronary arteries.

Patients are then transferred for monitoring to either a coronary care, high dependency or intensive care unit.

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

The SAPIEN 3 is a register trademarks of Edwards Lifesciences Corporation or its affiliates. There are other TAVI valves available in Australia, but these valves are self-expanded rather than balloon expanded, so do not employ a balloon catheter. Balloon expanded valves have been demonstrated to have different outcomes compared to self-expanded valves[7] [8]

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?

TAVI is currently included on the MBS for patients with symptomatic severe aortic stenosis who are at high risk of surgical aortic valve replacement (SAVR) or who are inoperable. TAVI is a new approach in Australia for treating patients who are have symptomatic severe aortic stenosis who are at intermediate risk for SAVR.

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):

It is anticipated that in nearly all cases that TAVI would be delivered only once in a lifetime.

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

It is not anticipated that additional resources or medical services would be delivered at the same time, other than those that would occur during the TAVI admission.

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

An interventional cardiologist or a cardiothoracic surgeon must perform the procedure

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

The service 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 cardiothoracic surgeons or interventional cardiologists who are accredited TAVI practitioners

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:

Cardiothoracic surgeons must have completed the Cardiothoracic Surgery Program and be eligible to be a Fellow of the Royal Australasian College of Surgeons or otherwise qualified to practice cardiothoracic surgery in Australia.

Interventional Cardiologists must have completed the Advanced Training Curriculum in Cardiology and be eligible to be a Fellow of the Royal Australasian College of Physicians or otherwise qualified to practice interventional cardiology in Australia.

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[7] Noorani et al *'Differences in Outcomes and Indications between SAPIEN and CoreValve Transcatheter Aortic Valve'* Interv Card Rev Vol 9 Issue 2 2014

[8] Wijeysundera H.C. *'Comparison of Outcomes of Balloon-Expandable Versus Self-Expandable Transcatheter Heart Valves foe Severe Aortic Stenosis'* Am J Cardiol 2017; 119: 1094-1099

Additionally, the Interventional cardiologist of cardiothoracic surgeon must be an accredited TAVI Practitioner. Accreditation is conducted by the Accreditation Committee appointed by Cardiac Accreditation Services Limited[9]

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

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

The service must be provided in a hospital that has been clinically accepted as being a suitable hospital in which Medicare Item number 38495 may be performed.[10]

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

The TAVI service may be provided in either a public or private hospital provided the hospital is clinically accepted as able to provide TAVI

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

- ☒ Yes
- ☐ No – please specify below

Specify further details here

[9] http://tavi.org.au/

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

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 comparator is SAVR with a bioprosthesis or mechanical aortic valve. As with TAVI, it is not anticipated that other resources would be required at the same time other than those that are provided during the SAVR admission

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

☒ Yes (please provide all relevant MBS item numbers below)

38488

VALVE REPLACEMENT with BIOPROSTHESIS OR MECHANICAL PROSTHESIS

Fee: $1,909.60

☐ No

38489

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

Fee: $2,271.05

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

Patients receiving SAVR will receive an echocardiogram at one month, 6 months and at 3 years. Complications of SAVR include stroke, heart failure, permanent pacemaker implantation, and other cardiovascular events. If these events occur, patients will receive the customary treatment and follow-up. It is also possible that a re-operation will be needed, although this is rare. Subsequent re-operation may be TAVI or SAVR. Please see the attached 'Clinical Pathway after SAVR

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

It will be instead of the nominated comparator

☐ Yes
☐ No

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

It is estimated that as many as 80 percent of intermediate risk patients may access TAVI, should the service be included on the MBS. Please see Questions 49 and 50 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):

The clinical pathway will be essentially the same after TAVI as it is for SAVR however survival at one year is higher for TAVI (92.6% vs 87%), major stroke is lower for TAVI (2.3% vs 5.9%) but pacemaker implantation

is slightly higher (12.4% vs 9.4%)[11]. It should also be noted that SAVR, as on open chest procedure necessarily will involve a longer hospital stay, including longer ICU/high dependency unit time than TAVI. Recovery time is also likely to be longer.

[11] Thourani VH et al *'Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis'* The Lancet April 3, http://dx.doi.org/10.1016/S0140-6736(16)30073-3

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 superior to SAVR in patients with symptomatic severe aortic stenosis of intermediate risk of surgery in terms of overall survival and incidence of disabling stroke. TAVI also results in significantly lower rates for new onset atrial fibrillation (AF), major bleeding events and renal failure

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:

Major Stroke

New onset AF

New permanent pacemaker

Major bleeding events

Major vascular complications

Renal Failure

Clinical Effectiveness Outcomes:

Overall Survival

Quality of Life

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

Osnabrugge estimated that 3.4% of the population over 75 years would have severe AS. Of those, 75.6% would be symptomatic. It is estimated that 15.8% of patients with severe symptomatic AS are at intermediate risk of surgery.[12] Thourani et al [13] estimated from the STS data set that 13.9% of patients who underwent SAVR were of intermediate risk. Assuming the higher Osnabrugge figure of 15.8%, we can estimate the number of intermediate risk patients who would be eligible for TAVI. To not underestimate the population, it will be assumed that the same risk identified in the over 75 population exists in the over 65 population.

Australian population over 65 years[14]

	2017	2018	2019
Australian Population over 65 years of age	**3,804,770**	**3,929,281**	**4,053,834**

An estimate of the number of patients who would be eligible for the proposed service can be made from the number of MBS item numbers that have been claimed for SAVR procedures. TAVI became available on the MBS in November 2017. This is likely to reduce the overall population that will receive SAVR past this date. Therefore, Medicare statistics prior to November 2017 have been accessed to avoid underestimating the population

In the year from Quarter 4 2016 to end Quarter 3 2017 MBS Item 38488 was claimed 2601 times and MBS Item 38489 was claimed 90 times. 80% of these patients were over 65 years old and likely to be eligible for TAVI.[15]

According to Australian Institute of Health and Welfare statistics[16], 926 patients received TAVI in Australia during 2015/2016. As TAVI was not included on the MBS at that time, these procedures were more likely to have been performed in the public sector. It is possible that some of these patients would have been treated in private hospitals should the option have been available. To avoid underestimation of the population, it is assumed that all these patients would have been treated in the private sector if TAVI had been available.

The following estimates are made using the utilisation of MBS item numbers 38488 and 38489 as a proportion of the population over 65. The same methodology is applied to TAVI procedures. Only 80% of patients receiving SAVR under these item numbers are 65 or older so this is likely to be a conservative estimate.

		2016	2017	2018	2019	2020
A	**Australian Population**	**3,686,083**	**3,804,770**	**3,929,281**	**4,053,834**	**4,183,738**

[12] Osnabrugge MS et al *'Aortic Stenosis in the Elderly. Disease Prevalence and Number of Candidates for Transcatheter Aortic Valve Replacement: A Meta-Analysis and Modelling Study'* JACC 2013 Vol. 62, No 11, 2013
[13] Thourani VH et al *'Contemporary real-world outcomes of surgical aortic valve replacement in 141,905 low-risk, intermediate-risk, and high-risk patients.'* Ann Thorac Surg 2015;99:55-61
[14] Australian Bureau of Statistics Population Projections Australia 2012. Series B
[15] http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp
[16] Australian Institute of Health and Welfare, Procedures and healthcare interventions (ACHI 9th edition), Australia, 2015-16

		2016	2017	2018	2019	2020
	over 65 years of age					
B	**MBS item numbers 38488 and 38489**	**2755**	**2843**	**2936**	**3029**	**3126**
C	**TAVI Procedures**	**926**	**955**	**987**	**1018**	**1051**
D	**Total AVR population (B+C)**	**3681**	**3798**	**3923**	**4047**	**4177**
C	**Intermediate Risk Group (15.8% of D)**	**581**	**600**	**619**	**639**	**659**

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

As this intervention is usually performed late in life, it is anticipated that the service would only be delivered once per patient

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

1 year

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

It is estimated that 659 patients would be eligible for the proposed service in 2020. It is however, unlikely that all these patients would access TAVI. Australian referral patterns are such that referral to a Heart Team is not yet routine. Therefore, if a patient is referred to a cardiologist or a surgeon who is not part of a TAVI Heart Team, the patient may not be given the option of receiving TAVI. This figure is therefore likely to be an overestimate.

Osnabrugge estimated that 80% of high risk/inoperable patients eligible for TAVI received the procedure. If we apply this figure to intermediate risk patients who are eligible, then in the first year, 527 patients would 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:

A TAVI procedure must be performed by a TAVI practitioner in a TAVI hospital. It is possible that there will be capacity restraints if there are not enough available facilities and trained medical staff to meet demand. It is likely that capacity will increase in coming years. However, assuming that capacity is available to meet demand, the following uptake is likely.

		2021	2022	2023
A	**Australian Population over 65**	**4,318,848**	**4,454,687**	**4,593,986**

		2021	2022	2023
	years of age			
B	Eligible Population	680	702	723
C	Patients accessing TAVI 80% X B	544	561	578

As access to TAVI is determined by the TAVI Heart Team, it is unlikely that there will be leakage to populations outside the eligible population.

PART 8 – COST INFORMATION

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

TAVI implants are currently included on the Prostheses List at $22,932.

Other cost items include the following MBS Item numbers

Cost Item	MBS Item Number	100% MBS Fee	75% Benefit
TAVI Case Conference -Organiser	6080	$50.15	$37.65
TAVI Case Conference Attendance X 3	6081	$37.40	$28.05
TAVI Procedure including all intraoperative diagnostic imaging	38495	$1,432.20	$1,074
Assistant	51303	$286.40	$214.80
Initiation of Anaesthesia	21941	$138.60	$103.95
Anaesthesia Time Units 1:41 to 1:45 hours	23073	$138.60	$103.95
ICU Attendance	13870	$362.10	$271.60
Transthoracic echocardiography	55113	$230.65	$173.00

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

The procedure will 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 will suffice for the new indication.

Category 3 – Therapeutic Procedures – Surgical Operations
Proposed 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

PART 9 – FEEDBACK

The Department is interested in your feedback.

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

Insert approximate duration here

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

☐ Yes
☐ No

(b) If no, provide areas of concern:

Describe areas of concern here

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

☐ Yes
☐ No

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

Insert feedback here

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

☐ Yes
☐ No

(b) If yes, please advise:

Insert feedback here