MSAC Application 1770

Valve-in-valve transcatheter aortic valve implantation using a balloon-expanding transcatheter heart valve system for patients with severe, symptomatic aortic stenosis

Application for MBS eligible service or health technology

MSAC Application Number:
1770

Application title:
Valve-in-valve transcatheter aortic valve implantation using a balloon-expanding transcatheter heart valve system

Submitting organisation:
Edwards Lifesciences Pty Limited

Submitting organisation ABN:
77098906873

Application description

Succinct description of the medical condition/s:
The target population comprises patients whose background problem is severe, symptomatic aortic stenosis. These patients have previously undergone surgical aortic valve replacement (SAVR), but are now experiencing symptomatic structural valve deterioration (SVD), with the bioprosthetic aortic valve failing and resulting in stenosis, insufficiency or both. A repeat aortic valve replacement is indicated. The patients have also been judged by a heart team, including a cardiothoracic surgeon, to be at high risk for open heart surgery; that is, ≥8% predicted risk of surgical mortality at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator. Only patients at high surgical risk are currently eligible as per the current regulatory approval issued by the Australian Therapeutic Goods Administration (TGA).

Succinct description of the service or health technology:
ViV TAVI is a minimally-invasive procedure. Compared to redo SAVR, an open procedure that involves cardio-pulmonary bypass, there is a lesser risk of mortality and other peri-operative complications, shorter length of hospital stay and faster recovery.

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?
Applicant

Are you applying on behalf of an organisation, or as an individual?
Organisation

Is the applicant organisation the organisation you are representing in the HPP today?
Yes

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?
No

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?
New

Please select any relevant MBS items.
38495 (Expansion or amendment to existing item)

What is the type of service or health technology?
Therapeutic

PICO Sets

PICO set	PICO set name
1	TAVI in patients who have previously undergone surgical aortic valve replacement (SAVR)
2	TAVI in patients who have previously undergone transcatheter aortic valve implantation (TAVI)

Population

Describe the population in which the proposed health technology is intended to be used:
The target population comprises patients whose background problem is severe, symptomatic aortic stenosis. These patients have previously undergone surgical aortic valve replacement (SAVR) or transcatheter aortic valve implantation (TAVI), but are now experiencing symptomatic structural valve deterioration (SVD), with the bioprosthetic aortic valve failing and resulting in stenosis, insufficiency or both. A repeat aortic valve replacement is indicated. The patients have also been judged by a heart team, including a cardiothoracic surgeon, to be at high risk for open heart surgery; that is, ≥8% predicted risk of surgical mortality at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator. Only patients at high surgical risk are currently eligible as per the current regulatory approval issued by the Australian Therapeutic Goods Administration (TGA).

Search and select the most applicable medical condition terminology (SNOMED CT):
773996000

Intervention

Name of the proposed health technology:
Valve-in-valve (ViV) TAVI BEV (Balloon Expanding Valve) using the Edwards SAPIEN 3 Ultra Transcatheter Heart Valve (THV) system.

Comparator

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). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:
The nominated comparator is redo SAVR using a surgical bioprosthetic valve.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:
Healthcare costs related to the index procedures, their complications and other relevant consequences over a specified time horizon.

Proposed MBS items

Proposed Item AAAAA

MBS item number:
38484

Proposed category:
THERAPEUTIC PROCEDURES

Proposed group:
SURGICAL OPERATIONS

Proposed item descriptor:
Aortic or pulmonary valve replacement with bioprosthesis or mechanical prosthesis, including retrograde cardioplegia (if performed), other than a service associated with a service to which item 11704, 11705, 11707, 11714, 18260, 33824,38816, 38828 or 45503 applies (H) (Anaes.) (Assist.)

Proposed MBS fee:
$1,576.45

Indicate the overall cost per patient of providing the proposed health technology:
$82,500.00

Please specify any anticipated out of pocket costs:
$0.00

Provide details and explain:
Fee is in line with the current MBS item 38495

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):
There is State-based funding in Public Hospitals.

In Private Hospitals patients can apply for ex-gratia funding through their Private Health Fund and these are assessed on a case-by-case basis.

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?
Superior

Please state what the overall claim is, and provide a rationale:
ViV TAVI is superior to redo SAVR as it provides significant improvements in short-term mortality, bleeding and length of hospital stay according to an umbrella meta-analysis of published meta-analyses by Aedma et al (2022).

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:
Approximately 9000 surgical AVR annually with a fail rate at 10 years of 1%

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):
90

Year 2 estimated uptake (%):
90

Year 3 estimated uptake (%):
90

Year 3 estimated uptake (%):
90

Estimate the number of patients who will utilise the proposed technology for the first year:
90

Optionally, provide details:
-

Will the technology be needed more than once per patient?
No, once only

Consultation

List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service:
- The Cardiac Society of Australia and New Zealand

List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service:
- The Cardiac Society of Australia and New Zealand

List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:
- Hearts 4 Hearts Australia

List the relevant sponsor(s) and/or manufacturer(s) who produce similar products relevant to the proposed service or health technology:
- Abbott Australasia Pty Ltd
- Medtronic

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?
No