

MSAC application 1799

Transcatheter tricuspid valve replacement in patients with severe, symptomatic tricuspid regurgitation despite optimal medical therapy

Application for MBS eligible service or health technology

HPP Application number:

HPP200253

Application title:

Transcatheter tricuspid valve replacement in patients with severe, symptomatic tricuspid regurgitation despite optimal medical therapy

Submitting organisation:

EDWARDS LIFESCIENCES PTY LIMITED

Submitting organisation ABN:

77098906873

Application description

Succinct description of the medical condition/s:

Tricuspid regurgitation (TR) is a heart valve condition where the tricuspid valve doesn't close properly, allowing blood to flow backward from the right ventricle into the right atrium. TR is classified by leaflet pathology as primary (due to abnormal tricuspid valve leaflets) or secondary (due to presence of left-sided heart disease); this classification system has recently been updated to include a further split of secondary TR by atrial and ventricular as well as to add lead-associated TR to capture TR attributable to cardiac implantable electronic devices. The severity of TR is categorised by the American Society of Echocardiography's (ASE) three-tiered grading scale to describe the different stages of TR including mild, moderate, and severe.

In Australia, there are approximately 25,500 patients with severe TR.

Succinct description of the service or health technology:

The EVOQUE Tricuspid Valve Replacement System is a minimally invasive transcatheter device designed to replace the tricuspid valve without open-heart surgery. It is delivered through a transfemoral approach using a specially designed delivery system. By replacing the dysfunctional tricuspid valve with a bioprosthetic valve, EVOQUE prevents backflow, effectively reducing TR severity and improving blood flow dynamics in the heart. This restoration of valve function relieves pressure on the right ventricle, improving its performance and reducing strain. Consequently,

TTVR slows or even reverses the progression of right-sided heart failure, a common and debilitating result of severe TR.

The TRISCEND II trial demonstrates unprecedented TR grade reduction, with 99.1% of TTVR recipients achieving \leq moderate TR and 95.3% achieving \leq mild TR at 1-year follow-up (core lab adjudicated). This as a result led to significant improvements in patient quality of life.

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

Applicant organisation name:

EDWARDS LIFESCIENCES PTY LIMITED

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?

Yes

Which list/schedule will the other health technologies be listed on?

Prostheses List

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

New

Relevant MBS items

Please select any relevant MBS items.

MBS item number	Selected reason type
56807	Prerequisite item
55126	Prerequisite item

MBS item number	Selected reason type
22051	Prerequisite item

What is the type of service or health technology?

Therapeutic

PICO set

PICO set: EVOQUE Tricuspid Valve Replacement

Population

Describe the population in which the proposed health technology is intended to be used:

The proposed population for this MSAC application are people with severe, symptomatic TR despite optimal medical therapy.

Tricuspid regurgitation (TR) is a heart valve condition where the tricuspid valve does not close properly, allowing blood to flow backward from the right ventricle into the right atrium, which places additional strain on the heart to pump blood effectively (Latib, Grigioni et al. 2018). The main underlying cause is often an enlarged right ventricle, typically due to conditions that increase pressure in the heart, such as heart failure, pulmonary hypertension, or cardiomyopathy (Arsalan, Walther et al. 2015). TR frequently remains asymptomatic until it becomes severe.

The prevalence of \geq moderate TR is estimated to be 2.6% in adults \geq 65 years old and imposes a considerable burden on patients, correlating with elevated rates of heart failure and mortality (Cahill, Prothero et al. 2021). As of 2020, approximately 4.2 million Australians (16% of the population) were aged 65 years and over (Australian Bureau of Statistics, 2022). Based on a prevalence rate of 2.6%, an estimated 109,200 people in this age group had moderate or severe TR. In an Australian study examining the distribution of TR severity, it was found that 5.9% of people have moderate TR and 1.8% have severe TR; therefore, amongst patients with at least moderate TR, severe TR accounts for 23% of cases (1.8%/7.7%) (Offen, Playford et al. 2022). Based on these epidemiological inputs, there are approximately 25,500 patients with severe TR in Australia.

The 1-year mortality in patients with \geq severe TR is reported to be 20% (Chorin, Rozenbaum et al. 2020, Messika-Zeitoun, Verta et al. 2020). Beyond the heightened mortality risk, individuals with TR encounter declines in their quality of life and

experience increased hospitalisation rates (Fujisawa, Kimura et al. 2022, Kumar, Byrne et al. 2023). Severe TR is associated with high morbidity and mortality, particularly in elderly patients with comorbidities such as atrial fibrillation and heart failure, resulting in significant clinical complications, including hepatic, renal, hematologic, and other sequelae (Webb, Chuang et al. 2022). The impact on patients is profound, often leading to substantial impairments in health-related quality of life (HRQoL) due to persistent and debilitating symptoms such as breathlessness, leg oedema, dyspnoea, ascites, and chest pain (Fender, Zack et al. 2018).

Severe TR remains a challenging condition with limited effective treatment options. Currently in Australia, treatment options involve either medical management (diuretic therapy) or surgical valve repair and replacement. Diuretic therapy aims to primarily provide symptomatic relief and prevent disease progression; however, outcomes are poor (Otto, Nishimura et al. 2021). Patients with severe TR are frequently considered inoperable due to comorbidities, meaning surgery is restricted to patients with a suitable risk profile (Otto, Nishimura et al. 2021). Additionally, research has revealed mortality after TR surgery is high, with risk of death up to 25% for patients undergoing open-heart surgery for isolated tricuspid valve replacement, leading many to forgo surgical treatment in favour of medication alone (Fender, Zack et al. 2018).

Select the most applicable Medical condition terminology (SNOMED CT):

Tricuspid valve regurgitation (disorder) | SNOMED CT: 44383004

Intervention

Name of the proposed health technology:

EVOQUE transcatheter tricuspid valve replacement

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 standard of care for these patients is optimised medical therapy, which typically consists of loop diuretics. This is in alignment with international guidelines and the

TRISCEND II RCT. In the TRISCEND II pivotal trial, patients without the EVOQUE device were on stable oral diuretic medications, most commonly Frusemide 40mg. Healthcare resources delivered with OMT include:

- Regular monitoring of weight, blood pressure, and symptom exacerbation
- Full blood tests for renal function and electrolytes
- Periodic cardiac specialist follow-up
- Echocardiographic monitoring

In current Australian practice, very few with TR are able to undergo surgical intervention due to factors such as advanced age, TR severity, liver dysfunction, other cardiac conditions such as concomitant mitral valve disease, and other chronic conditions such as AF, kidney dysfunction, and ischaemic coronary disease. In addition, surgical treatment of isolated TR is challenging due to factors such as right ventricular dysfunction and hepatorenal dysfunction caused by chronic venous hypertension, often in patients who have previously undergone cardiac surgery. As a result, the uptake of tricuspid valve surgery is very low and surgery is not considered a relevant comparator for this submission.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

As a result of the EVOQUE TTVR procedure, patients have a reduced degree of TR leading to improved quality of life and reduced risk of hospitalisation for heart failure.

The primary analysis from TRISCEND II demonstrated that EVOQUE is superior to OMT based on an improvement in both clinical events and quality of life.

In addition to the hierarchical composite primary endpoint from TRISCEND II, the submission will present the individual components of the composite. This approach aligns with the outcomes presented in previous MSAC considerations of structural heart interventions such as transcatheter mitral valve repair using PASCAL or MitraClip. In MSAC Application 1662.2 for PASCAL, the primary safety endpoint was defined as major adverse events (MAEs) inclusive of cardiovascular mortality, stroke, myocardial infarction, need for new renal replacement therapy, severe bleeding, and re-intervention for study device-related complications. These endpoints are available from the TRISCEND II RCT and are proposed to be applicable to the TTVR procedure. Similar to the TMVR procedure, TR reduction at 1 year will be presented. Other efficacy endpoints include reduction in heart failure hospitalisations, improvement in

health-related quality of life (measured using the KCCQ-OS), NYHA functional class, and 6-minute walk distance.

Proposed MBS items

Proposed item:

AAAAA

Category number:

3

Category description:

Therapeutic procedure

Proposed item descriptor:

Transcatheter tricuspid valve replacement using the EVOQUE tricuspid valve replacement system, including intraoperative diagnostic imaging if:

(a) The patient has each of the following risk factors:

- (i) Symptomatic, severe, or greater TR that has not responded adequately to OMT, defined as grade 3+;
- (ii) left ventricular ejection fraction of 25% or more.

(b) The patient is deemed suitable for TTVR by a qualified multidisciplinary heart team, following a detailed assessment of comorbidities and expected benefits.

(c) The Service is performed:

- (i) by an accredited interventional cardiologist or cardiothoracic surgeon trained and certified by the TTVR Accreditation Committee.
- (ii) via transfemoral venous approach.
- (iii) in a hospital accredited by the TTVR Accreditation Committee to ensure appropriate facilities, personnel, and postoperative care.

(d) a service to which this item applies, or any other item covering TTVR, must not have been provided to the patient before.

(H) (Anaes.) (Assist.)

Proposed MBS fee:

\$1,800

Indicate the overall cost per patient of providing the proposed health technology:

\$1,800

Please specify any anticipated out of pocket expenses:

\$0.00

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

TTVR is currently not funded in Australia

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:

Efficacy: Superior

Safety: Non-inferior

The EVOQUE device demonstrates superior efficacy over OMT in reducing TR and improving health outcomes. In terms of safety, EVOQUE is considered non-inferior to OMT for long-term adverse events, with manageable procedural risks.

The clinical claim is based on analysis of individual measures contributing to the composite outcome. The hierarchical composite measure included:

- Death from any cause
- Durable implantation of a right ventricular assist device or heart transplantation
- Tricuspid-valve surgery or percutaneous tricuspid intervention after any index intervention
- Annualised rate of hospitalisation for heart failure
- Health-related quality of life measured using the Kansas City Cardiomyopathy Questionnaire overall summary (KCCQ-OS)
- NYHA functional class
- 6-minute walk distance

As described above, the outcomes presented in this application will also include individual components of the composite measure.

Rationale: A pivotal trial involving 400 patients with symptomatic severe TR demonstrated significant clinical benefit with the EVOQUE system over OMT. The primary composite outcome showed a substantial advantage for EVOQUE, evaluated by hierarchical composite safety and effectiveness endpoints at 1 year.

Reduction in TR grade was a pre-specified secondary endpoint. The EVOQUE system significantly reduced TR severity, with 95.3% of patients achieving mild or less TR at 1 year compared to 2.3% in the control group.

The safety profile demonstrates that early procedural risks are mitigated over time, with comparable long-term outcomes. TTVR provided superior clinical benefits, with 62.1% of TTVR patients experiencing clinical benefit compared to 30.7% in the OMT group, offering a twofold greater likelihood of clinical benefit.

Estimated utilisation

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

The prevalence of \geq moderate TR is estimated to be 2.6% in adults \geq 65 years old and imposes a considerable burden on patients, correlating with elevated rates of heart failure and mortality (Cahill, Prothero et al. 2021). As of 2020, approximately 4.2 million Australians (16% of the population) were aged 65 years and over (Australian Bureau of Statistics, 2022). Based on a prevalence rate of 2.6%, an estimated 109,200 people in this age group had moderate or severe TR. In an Australian study examining the distribution of TR severity, it was found that 5.9% of people have moderate TR and 1.8% have severe TR; therefore, amongst patients with at least moderate TR, severe TR accounts for 23% of cases (1.8%/7.7%) (Offen, Playford et al. 2022). Based on these epidemiological inputs, there are approximately 25,500 patients with severe TR in Australia. The uptake percentages should be estimated based on: current surgical ineligibility rates, center availability, training requirements and patient preferences. Given that the resources, training requirements and center availability is expected to be similar to the Mitraclip device, the estimated uptake is based on actual % uptake from the Mitraclip device compared to rates of MR (MBS item numbers 38461 and 38463).

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

Year 1 estimated uptake (%):

REDACTED%

Year 2 estimated uptake (%):

REDACTED%

Year 3 estimated uptake (%):

REDACTED%

Year 4 estimated uptake (%):

REDACTED%

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

REDACTED Patients

Optionally, provide details:

Calculation limited by:

- Center availability and certification requirements
- Physician training timelines
- Patient selection criteria (Severe or greater TR despite OMT)
- Gradual adoption of new technology

Will the technology be needed more than once per patient?

No, once only

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entity who provides the health technology/service:

Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS)

Cardiac Society of Australia and New Zealand (CSANZ)

Entity who requests the health technology/service:

Cardiac Society of Australia and New Zealand (CSANZ)

Australian Medical Association (AMA)

Royal Australasian College of Physicians (RACP)

Entity who may be impacted by the health technology/service:

Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS)

Australian Cardiovascular Health and Rehabilitation Association

Australian Medical Association (AMA)

Australian Society of Anaesthetists

Cardiac Society of Australia and New Zealand (CSANZ)

Royal Australasian College of Physicians (RACP)

Society of Cardiovascular Anaesthesiologists

Patient and consumer advocacy organisations relevant to the proposed service/health technology:

Australian Cardiovascular Alliance

Australian Patient Organisation Network

Consumers Health Forum of Australia

Hearts4Heart

National Heart Foundation of Australia

Entity who produces similar products:

Abbott Vascular

Boston Scientific

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?

Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

No

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

Class III

Is the therapeutic good to be used in the service exempt from the regulatory requirements of the Therapeutic Goods Act 1989?

No

Is the therapeutic good classified by the TGA as for Research Use Only (RUO)?

No