

## **MSAC Application 1799**

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

**Applicant: Edwards Lifesciences Pty Ltd**

## **PICO Confirmation**

## Summary of PICO criteria to define question to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Table 1 PICO for transcatheter tricuspid valve replacement in patients with severe, symptomatic tricuspid regurgitation despite optimal medical therapy

Component	Description
Population	Patients with primary or secondary tricuspid regurgitation (TR) graded at least severe, as determined by echocardiography, with symptoms (New York Heart Association [NYHA] functional class II or greater) that persist despite optimal medical therapy (OMT), and who have left ventricular ejection fraction (LVEF) of 25% or more, and are deemed by a qualified multidisciplinary heart team to be suitable for isolated transcatheter tricuspid valve replacement (TTVR)
Intervention	Transcatheter tricuspid valve replacement in addition to continued OMT
Comparator	Continued OMT alone
Outcomes	<p><b>Safety outcomes:</b></p> <ul style="list-style-type: none"> <li>• major cardiovascular (CV) events (myocardial infarction, stroke, CV death)</li> <li>• severe bleeding</li> <li>• major access site and vascular complications</li> <li>• major cardiac structural complications (e.g. coronary structure perforation)</li> <li>• arrhythmia or conduction disorder requiring permanent pacing</li> <li>• new need for renal replacement therapy</li> <li>• conversion to surgery</li> <li>• tricuspid valve reintervention (percutaneous or surgical)</li> <li>• prosthetic valve dysfunction</li> </ul> <p><b>Efficacy/effectiveness outcomes:</b></p> <ul style="list-style-type: none"> <li>• mortality (all cause, CV)</li> <li>• hospitalisation for heart failure</li> <li>• implantation of a right ventricular assist device or heart transplantation</li> <li>• change in TR grade</li> <li>• quality of life using disease-specific tools (e.g. Kansas City Cardiomyopathy Questionnaire [KCCQ]) and generic tools (e.g. EuroQol 5-dimension tool [EQ-5D] or 36-item Short Form Health Survey [SF-36])</li> <li>• health status (New York Heart Association [NYHA] functional class and 6-minute walk test [6MWT])</li> <li>• change in medical therapy (dose, frequency, type)</li> </ul> <p><b>Healthcare resources:</b></p> <ul style="list-style-type: none"> <li>• cost of tricuspid valve prosthesis and other consumables</li> <li>• cost to deliver TTVR intervention</li> <li>• cost associated with changes in clinical management (testing required before the procedure, length of hospital stay, post-discharge rehabilitation)</li> <li>• cost associated with management of complications (including reintervention)</li> </ul>

Component	Description
	<b>Cost-effectiveness:</b> <ul style="list-style-type: none"> <li>• cost per life year gained</li> <li>• cost per quality-adjusted life year (QALY) gained</li> </ul> <b>Total Australian government healthcare costs</b> <ul style="list-style-type: none"> <li>• total cost to the Medical Benefits Schedule (MBS)</li> <li>• total cost to other government health budgets, including the Pharmaceutical Benefits Scheme (PBS)</li> </ul>
Assessment questions	What is the comparative safety, comparative effectiveness and cost-effectiveness of TTVR in addition to continued OMT versus OMT alone in patients with severe, symptomatic TR despite OMT who are suitable for TTVR?

## Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of transcatheter tricuspid valve replacement (TTVR) for the treatment of severe, symptomatic tricuspid regurgitation (TR) despite optimal medical therapy (OMT) was received from Edwards Lifesciences Pty Limited by the Department of Health and Aged Care.

The clinical claim made in the application was that TTVR using the Edwards EVOQUE Tricuspid Valve Replacement System (herein referred to as the EVOQUE system) is superior with respect to efficacy (in terms of health status) and non-inferior with respect to safety (long-term adverse events) compared to OMT without TTVR.

## PICO criteria

### *Population*

The proposed population is patients with TR (primary or secondary) graded at least severe, as determined by echocardiography, with symptoms (New York Heart Association [NYHA] functional class II or greater) that persist despite OMT, and who have left ventricular ejection fraction (LVEF) of 25% or more. To be eligible for the intervention, patients must also be deemed by a qualified multidisciplinary heart team to be suitable for isolated TTVR.

The application did not specify that the patient population had to be inoperable or at high surgical risk but acknowledged that open heart surgery would be an unsafe or unacceptable option for the majority of patients with severe, symptomatic TR.

The assessment group added the requirement for echocardiography to determine TR severity, and confirmation of symptoms using NYHA functional class. At the pre-PASC meeting,<sup>1</sup> the applicant confirmed that the intervention is intended for patients eligible for isolated TTVR, without concomitant

<sup>1</sup> Discussed at the Pre-PASC meeting with the applicant on 27 February 2025.

cardiovascular procedures, such as coronary artery bypass grafts, other valvular operations, aortic operations, or ventricular assist device implantations.

The proposed population is consistent with the study population in the pivotal randomised controlled trial (RCT) that evaluated the safety and efficacy of the EVOQUE system (in addition to continued OMT) versus OMT alone, referred to as the TRISCEND II Pivotal Trial ([NCT04482062](https://clinicaltrials.gov/ct2/show/study/NCT04482062); Grayburn et al. 2024). Although high surgical risk was not an explicit exclusion criterion in TRISCEND II, the applicant's clinical expert advised that it was implicit in the trial design because the local heart team would have assessed whether surgery was the most suitable option for the patient when evaluating the appropriateness of TTVR.<sup>1</sup>

Key exclusion criteria for enrolment in TRISCEND II included:

- age <18 years
- anatomy precluding proper device delivery, deployment or function
- evidence of severe right ventricular (RV) dysfunction
- severe renal insufficiency or severe pulmonary hypertension
- severe aortic, mitral and/or pulmonic valve stenosis and/or regurgitation.

Although the proposed population does not specify these exclusion criteria, the application noted that it is expected that these would be realised in practice through the multidisciplinary heart team who will be required to determine eligibility for the procedure.

*PASC agreed with the proposed patient population, noting the requirement for a multidisciplinary heart team to determine suitability for TTVR is crucial for optimising patient outcomes. PASC noted the applicant's clinical experts considered that it was unnecessary for the population description to contain an exhaustive list of contraindications and trial exclusion criteria given the proposed role of the multidisciplinary heart team, who are best placed to consider each individual patient's risk-benefit profile. However, PASC agreed that the requirement for LVEF of 25% or more was appropriate, noting that LVEF is an extremely important independent marker of survival.*

*PASC discussed whether surgical ineligibility should be specified in the population, noting that isolated tricuspid valve surgery is a high-risk operation and surgical risk prediction tools are not accurate for assessing that risk. PASC acknowledged that clinical practice guidelines advise that surgery should be offered in patients with severe, symptomatic TR; however, current guidelines do not provide clear advice on patient selection nor the threshold for surgical intervention. PASC noted that surgeons are often reluctant to offer isolated tricuspid valve surgery because of the high mortality risk and uncertain outcomes in this cohort of patients. PASC decided that surgical ineligibility or risk should not be a criterion for the population and any decisions about suitability for surgical or transcatheter intervention should be at the discretion of the multidisciplinary heart team.*

#### *Severe 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 et al. 2018). It can be caused by a variety of factors, which are typically classified into primary and secondary causes. Primary TR may occur due to direct damage to tricuspid valve leaflets (such as from infective endocarditis, rheumatic heart disease, blunt chest trauma, carcinoid, drugs and radiation) or a congenital condition like Ebstein's anomaly (Otto et al. 2021). Secondary (functional) TR accounts for approximately 90% of patients with TR (Vahanian et al. 2022). The most common secondary

cause is RV remodelling due to pressure or volume overload, which occurs in conditions such as left-sided heart disease, chronic pulmonary hypertension or dilated cardiomyopathies (Otto et al, 2021). Classification of secondary TR has recently been split further to account for ventricular and atrial causes, as well as lead-associated TR to capture TR attributable to cardiac implantable electronic devices (Hahn et al. 2023).

The severity of TR is graded according to American Society of Echocardiography (ASE) guidelines (Zoghbi et al. 2017) into mild, moderate, or severe. More recently, the grading system has been expanded to a 5-grade scale, providing a more precise classification for TR cases that are severe or greater (Hahn et al. 2023). In clinical practice, severe TR can be used as an umbrella term that includes severe, massive and torrential grades.

The 1-year mortality in patients with at least severe TR is reported to be 20% (Chorin et al. 2020; Messika-Zeitoun et al. 2020). In addition to the increased risk of death, these patients experience a decline in quality of life and higher hospitalisation rates (Fujisawa et al. 2022; Kumar et al. 2022). Severe TR can lead to a range of symptoms, primarily due to fluid overload and right heart dysfunction. Common symptoms include dyspnoea, fatigue, weakness, peripheral oedema, ascites and chest discomfort or pain. Severe TR is particularly associated with significant morbidity and mortality in elderly individuals with comorbidities such as atrial fibrillation and heart failure, where it can lead to serious complications, including hepatic, renal, and haematologic dysfunction (Webb et al. 2022).

The prevalence of moderate or severe TR is estimated to be 2.6% in adults aged 65 years and older (Cahill et al. 2021). An Australian study on TR severity distribution found that among patients with at least moderate TR, 23% had severe TR (Offen et al. 2022). Based on these epidemiological inputs, the application estimated there are approximately 25,500 patients with severe TR in Australia.

#### *Investigation and assessment of TR severity*

Clinical evaluation typically begins with a review by the general practitioner (GP) of the patient's history for conditions associated with TR. The patient will generally be referred to a cardiologist if the presence of TR is suspected, who in turn may refer the patient to either an interventional cardiologist or a cardiothoracic surgeon if intervention is required.

Echocardiography is currently the gold standard for evaluating the mechanism and severity of TR. Transthoracic echocardiography (TTE) is used for the initial diagnosis. A 3D echocardiography allows assessment of RV size and function, RV systolic pressure, right atrial size and estimated pressure, and left-sided heart disease as well as visualisation of all leaflets simultaneously. For significant TR, transesophageal echocardiography (TOE) is recommended and allows a complementary image, including both mid-oesophageal and trans-gastric views. In cases of poor echocardiographic quality or discordant findings, additional imaging modalities such as cardiac magnetic resonance imaging (MRI) or computed tomography (CT) can be used for further clarification.

#### *Current management of severe, symptomatic TR*

In Australia, treatment for severe TR currently includes medical therapy, surgical valve repair or replacement through open-heart or minimally invasive surgery, and more recently, transcatheter tricuspid valve intervention (TTVI).

Most patients rely on medical therapy alone to treat the symptoms of TR. According to both the American Heart Association/American College of Cardiology (AHA/ACC) and the European Society of Cardiology/and European Association for Cardiothoracic Surgery (ESC/EACTS) guidelines for the management of heart valve disease, diuretics (typically loop diuretics) may be beneficial for patients with severe TR and signs of right-sided heart failure to decrease volume overload (Otto et al. 2021; Vahanian et al. 2022). However, diuretics do not have an established role in preventing or delaying TR progression and the American and European guidelines contain no class 1 recommendations for medication management.

Current AHA/ACC guidelines include a class 1 recommendation for tricuspid valve surgery in patients with severe TR (regardless of symptoms) undergoing left-sided valve surgery (Otto et al. 2021). Isolated tricuspid valve surgery is considered beneficial to reduce symptoms and recurrent hospitalisations in selected patients with severe TR (class 2 recommendations). Current ESC/EACTS guidelines include class I recommendations for tricuspid valve surgery in patients with severe primary TR undergoing left-sided valve surgery, and patients with isolated severe primary TR without severe RV dysfunction (Vahanian et al. 2022). The European guidelines advise that the benefit of surgical correction of isolated secondary TR compared to medical treatment is not well established, but surgery should be considered for selected severe, symptomatic patients who are appropriate for surgery.

Guideline recommendations result in most tricuspid valve repairs or replacements being performed alongside left heart surgery, primarily mitral valve surgery. Tricuspid valve repair with a prosthetic ring (annuloplasty) is the standard of care surgical treatment and is preferred over tricuspid valve replacement as it carries higher overall survival (Vahanian et al. 2022). A range of annuloplasty devices differing in form and flexibility are available in Australia.

In the United States, nearly 90% of tricuspid valve procedures are repairs, while the number of replacements has declined over recent decades (Zoghbi et al. 2024). However, for isolated tricuspid valve procedures, replacements remain more common, likely due to the late presentation of isolated disease. The 2021 ESC/EACTS guidelines advise that replacement with a prosthetic valve should only be considered when annuloplasty is not feasible, such as when the tricuspid valve leaflets are tethered and the annulus severely dilated (Vahanian et al. 2022). Both mechanical and bioprosthetic valves can be used, though bioprosthetic valves are generally preferred for patients with shorter anticipated survival or comorbidities that may lead to further surgical procedures, and those who are at increased risk for bleeding complications (Vahanian et al. 2022).

In real-world practice, TR surgical intervention is only carried out in a select group of patients due to high operative risk related to late-stage disease upon referral and/or multiple comorbidities (Latib et al. 2018; Vahanian et al. 2022). Operative mortality rate for severe isolated TR is high (8% to 20%; Otto et al. 2021), leading many patients to forgo surgical treatment in favour of medication alone.

Of relevance to the application, the 2021 ESC/EACTS guidelines include a class IIb recommendation that TTVI may be considered by the heart team at experienced heart valve centres in symptomatic, inoperable, anatomically eligible patients in whom symptomatic or prognostic improvement can be expected (Vahanian et al. 2022).

TTVI can be broadly categorised into devices for TTVR or transcatheter tricuspid valve (TTV) repair. There are 2 types of TTVR: orthotopic and heterotopic. Orthotopic TTVR involves positioning the prosthetic valve

in the tricuspid annulus, while heterotopic TTVR involves positioning the prosthetic valve in the superior vena cava and/or inferior vena cava (also referred to as caval or bicaval valve implantation). TTV repair includes tricuspid edge-to-edge repair (TEER) devices, which bridge gaps between leaflets, and annulus-reshaping devices, designed to reduce annular dilation and restore its crescent shape.

### Intervention

The intervention proposed in the application is TTVR using the EVOQUE system in addition to continued OMT.

TTVR involves the use of a minimally invasive transcatheter device designed to replace the native tricuspid valve without the need for open-heart surgery. The artificial tricuspid valve is delivered through a transfemoral approach using a specially designed delivery system. By replacing the dysfunctional tricuspid valve with a bioprosthetic valve, TTVR prevents backflow of blood into the right atrium, reducing TR severity and improving blood flow dynamics in the heart.

Most TTVI devices are still in the early stages of development and not yet registered in Australia. Table 2 provides a non-exhaustive list of TTVI devices currently available or under investigation.

**Table 2 TTVI devices currently available or under investigation**

Device	Brief description	Delivery	Pivotal evidence	Registration
<b>Valve replacement (orthotopic)</b>				
EVOQUE (Edwards Lifesciences, USA)	Self-expanding bioprosthetic valve; bovine pericardium, nitinol frame with fabric skirt	Transfemoral	<b>Randomised:</b> TRISCEND II Pivotal Trial (NCT04482062) EVOQUE + MT vs MT alone	TGA approval (2025) FDA approval (2024) CE Mark
INTREPID (Medtronic, USA)	Self-expanding bioprosthetic valve; bovine pericardium, nitinol dual stent frame	Transfemoral	Non-randomised: INTREPID study	-
LuX-Valve and LuX-Valve Plus (Jenscare Biotechnology, China)	Self-expanding bioprosthetic valve; bovine pericardium, nitinol frame	Transatrial	Non-randomised: TRAVEL trial	-
Navi-GATE (NaviGate Cardiac Structures, USA)	Self-expanding bioprosthetic valve; equine pericardium, nitinol frame	Transatrial	Non-randomised: Navi-GATE study	-
<b>Caval valve implant (heterotopic)</b>				
SAPIEN 3 (Edwards Lifesciences, USA)	Bioprosthetic valve; bovine pericardium mounted onto a balloon-expandable cobalt-chromium stent	Transfemoral	Limited data for tricuspid valve use (off-label)	<b>Off-label for TTVR</b> TGA approval (from 2019) FDA approval (from 2015) CE Mark
<b>Bicaval valve implant (heterotopic)</b>				
TRICENTO (New Valve Technology, Germany)	Custom made bicaval covered stent, extends from IVC into SVC; nitinol frame, porcine pericardium	Transfemoral	Non-randomised: TRICENTO study	-

Device	Brief description	Delivery	Pivotal evidence	Registration
TricValve (P + F Products, Austria)	2 independent self-expanding valves implanted in SVC and IVC; nitinol frame, bovine pericardium leaflets	Transfemoral or transjugular	Non-randomised TRICUS trial TRICAV I study	CE Mark
Trillium Bioprosthetic Valve (Innoventric Ltd, Israel)	Self-expandable bioprosthetic valve implanted in SVC and IVC; bare metal stent coated with a Trillium polymer	Transfemoral, transjugular or transatrial	Non-randomised: Innoventric Trillium EFS	-
<b>Leaflet-directed repair (coaptation)<sup>a</sup></b>				
PASCAL (Edwards Lifesciences, USA)	Edge-to-edge repair with concomitant central woven nitinol spacer	Transfemoral	<b>Randomised:</b> CLASP II TR trial (NCT04097145) PASCAL + MT vs MT alone	TGA approval (2023) FDA approval for TMV repair only (2022) CE Mark
TriClip (Abbott Vascular, USA)	Edge-to-edge repair replicating Alfieri stitch; cobalt-chromium and nitinol	Transfemoral	<b>Randomised:</b> TRILUMINATE Pivotal Trial (NCT03904147) TriClip + MT vs MT alone	TGA approval (from 2021) FDA approval (2024) CE Mark
<b>Annulus-reshaping repair<sup>b</sup></b>				
Cardioband (Edwards Lifesciences, USA)	Adjustable band that mimics ring annuloplasty, Stainless steel	Transfemoral	Non-randomised: Tri-BAND trial Tri-REPAIR trial	CE Mark

Source: Collated by the assessment group from web searches and information contained in Davidson (2024); Nagraj et al. (2022); Rahgozar et al. (2021); Scott (2024); Seligman et al. (2023).

CE = Conformité Européenne (European Conformity); EFS = Early Feasibility Study; FDA = US Food and Drug Administration; IVC = inferior vena cava; MT = medical therapy; SVC = superior vena cava; TGA = Therapeutic Goods Administration; TMV = transcatheter mitral valve; TR = tricuspid regurgitation; TTVR = transcatheter tricuspid valve replacement; TTVI = transcatheter tricuspid valve intervention; USA = United States of America.

a FORMA Spacer (Edwards Lifesciences) TTV repair device is no longer available.

c TriCinch (4Tech) and Trialign (Mitralign) annuloplasty devices are no longer available.

### Implantation procedure

TTVR should only be performed as an inpatient procedure at specialised cardiac centres (public or private) with prompt access to facilities with the necessary equipment, instruments, supplies and personnel to perform emergency tricuspid valve surgery, if required. Access to cine fluoroscopy and TOE is required throughout the implantation procedure. The implantation procedure should only be performed by appropriately trained and certified heart specialists (interventional cardiologists or cardiothoracic surgeons) who have expertise in structural heart procedures and experience in related catheter-based procedures.

The application proposed formal accreditation of the centre where TTVR is performed and the heart specialists who perform the procedure, comparable to the accreditation requirements for transcatheter aortic valve implantation (TAVI) and transcatheter mitral valve repair (TMVr).

*PASC agreed that the intervention should be limited to cardiologists with specific skills at tertiary cardiac centres, and that a formal training and accreditation process is desirable, together with an ongoing surveillance program similar to TAVI.*



The implantation procedure is performed under general anaesthesia. The patient is intubated and a TOE probe is inserted and positioned. After gaining femoral vein access, a combination of fluoroscopic and echocardiographic guidance is used to advance the valve delivery catheter over a guidewire and into the right ventricle for deployment of the valve. The selected echocardiographic views and fluoroscopic guidance are used to monitor expansion of the prosthesis, leaflet capture, and assure proper positioning throughout the deployment process. After deployment and release of the new valve prosthesis, the delivery catheter is fully retracted and venous access is closed.

Proper positioning and functioning of the artificial valve, including the assessment of any paravalvular leakage, is confirmed by TOE. Before the patient is discharged from the hospital, continuous electrocardiogram (ECG) is used to monitor for any conduction disturbances.

Patients who receive TTVR should be maintained on anticoagulant/antiplatelet therapy to minimise the risk of valve thrombosis or thromboembolic events. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis.

The Instructions For Use (IFU) for the EVOQUE system notes that long-term durability has not been established for the EVOQUE valve and regular medical follow up is advised to evaluate valve performance. According to the application, follow-up assessments are performed at discharge, 30 days, 3 months, 6 months, 1 year, and annually up to 5 years post-procedure. Follow-up imaging tests may include echocardiograms to monitor the valve and cardiac function.

*PASC noted potential issues around access to care and follow-up assessments for patients living outside metropolitan locations. PASC were advised by the applicant's clinical experts that patients may not need to return to capital cities for follow up, which can be performed by specialists at large regional centres. PASC noted that access and follow-up issues for patients living in rural and remote locations are not unique to TTVR. The clinical experts advised that attempts to address health inequity will be in line with other technologies that require specialist intervention and follow up, including initiatives such as outreach programs and rural clinics serviced by telehealth or visiting specialists.*

#### *Expected uptake of the technology*

The application claimed that given the resources required, training and centre availability, uptake of TTVR in older patients with severe TR is likely to be similar to the uptake of TMVr in elderly patients with severe mitral valve regurgitation. According to the utilisation estimates provided in the application, uptake rates of TMVr over the first 4 years of listing ranged from 0.10% to 0.81% based on utilisation of MBS items 38461 and 38463; this equates to 26 to 206 patients per year receiving TTVR.

*PASC noted that the number of patients who would receive TTVR is uncertain, but the procedure is likely to be small volume, with lower utilisation than transcatheter mitral valve interventions.*

#### *Regulatory status*

The EVOQUE system is the only TTVR device currently included in the Australian Register of Therapeutic Goods (ARTG). Table 3 shows the indication approved by the Therapeutic Goods Administration (TGA). This wording is consistent with the indication approved by the US Food and Drug Administration (FDA).

The EVOQUE system is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen, who have active bacterial endocarditis or other active infections, or who have untreatable hypersensitivity to nitinol alloys.

**Table 3 ARTG summary for the EVOQUE system**

<b>Product name</b>	EVOQUE Tricuspid Valve Replacement System - Tricuspid transcatheter heart valve bioprosthesis
<b>Sponsor</b>	Edwards Lifesciences Pty Ltd
<b>ARTG ID</b>	483625
<b>ARTG start date</b>	21 March 2025
<b>Product category</b>	Medical Device Class III
<b>GMDN</b>	65121 Tricuspid transcatheter heart valve bioprosthesis
<b>Functional description</b>	The Edwards EVOQUE tricuspid valve replacement system is designed to replace the native tricuspid valve in patients with tricuspid valve regurgitation without the need for conventional open-heart surgery.
<b>Intended purpose</b>	The EVOQUE tricuspid valve replacement system is indicated for the improvement of health status in patients with symptomatic severe tricuspid regurgitation despite being treated optimally with medical therapy for whom tricuspid valve replacement is deemed appropriate by a Heart Team.
<b>Specific conditions</b>	No specific conditions

Source: [ARTG Public Summary](#), accessed 18 April 2024.

ARTG = Australian Register of Therapeutic Goods; GMDN = Global Medical Device Nomenclature; ID = identification number.

The Edwards SAPIEN 3 Transcatheter Heart Valve System (ARTG ID 471906) was primarily designed for aortic valve replacement but can be used in the tricuspid position, particularly for patients who have a degenerated surgical tricuspid bioprosthetic valve and need valve-in-valve replacement. However, any use in the tricuspid position would be considered off-label in Australia.

Two TTV repair devices – the PASCAL Precision System and the TriClip Transcatheter Tricuspid Valve Repair System – are registered for use in Australia (Table 4). There is some use of these technologies in the public health system but limited use in the private setting.<sup>2</sup>

**Table 4 TTVI systems included in the ARTG**

<b>Product Name</b>	<b>PASCAL Precision System</b>	<b>TriClip Transcatheter Tricuspid Valve Repair System</b>
<b>Sponsor</b>	Edwards Lifesciences Pty Ltd	Abbott Medical Australia Pty Ltd
<b>ARTG ID</b>	<a href="#">410289</a> – PASCAL Precision System – PASCAL ACE Implant System – Heart valve clip <a href="#">410288</a> – PASCAL Precision System – Implant System – Heart valve clip <a href="#">410290</a> – PASCAL Precision System – Guide Sheath – Heart valve clip	<a href="#">444061</a> – TriClip G4 Clip Delivery System – Mitral valve clip <sup>a</sup> <a href="#">444062</a> – TriClip Steerable Guide Catheter - Catheter, intravascular, guiding
<b>GMDN</b>	57790 Heart valve clip	57790 Heart valve clip 17846 Catheter, intravascular, guiding
<b>Category</b>	Medical Device Class III	Medical Device Class III
<b>Effective Date</b>	9 June 2023	20 March 2024

<sup>2</sup> The PASCAL System was listed on the Prescribed List in March 2025 on the condition that use is restricted to transvenous mitral valve repair (MBS item 38461).

Product Name	PASCAL Precision System	TriClip Transcatheter Tricuspid Valve Repair System
Intended Purpose	The PASCAL Precision system is intended to repair an insufficient mitral and/or tricuspid valve via percutaneous reconstruction through tissue approximation. The PASCAL Precision system percutaneously delivers the implant to the valve via a femoral vein access using a transvenous, transseptal (mitral) and transvenous (tricuspid) approach.	The TriClip™ G4 System is intended for reconstruction of the insufficient tricuspid valve through tissue approximation. The TriClip device is indicated for patients with severe tricuspid regurgitation who are symptomatic despite medical therapy with valve anatomies that are conducive for transcatheter repair and who have been determined to be at high or greater estimated risk for tricuspid valve surgery by a Heart Team.
Specific Conditions	No specific conditions	Final study reports of the 'TRILUMINATE Pivotal Study' and 'BRIGHT EU Post Approval Study' with a 5-year follow-up must be provided by 31st July 2028. The final study reports must be accompanied by the manufacturer's analysis of the data, with redlined changes made to the clinical evaluation report (CER) and risk management documents based on the final study results.

Source: Australian Register of Therapeutic Goods, accessed 20 February 2025

ARTG = Australian Register of Therapeutic Goods; GMDN = Global Medical Device Nomenclature; TTVI = transcatheter tricuspid valve intervention.  
a The functional description and intended purpose do not align with this device being named a mitral valve clip.

#### *Funding of the device*

The application stated that the TTVR device is not currently funded in Australia.

The cost of the EVOQUE system – according to the cost breakdown provided with the application – is \$REDACT. The applicant confirmed their intention to apply to list the EVOQUE system on the Prescribed List of Medical Devices and Human Tissue Products (PL) in parallel with the MSAC application process.<sup>3</sup>

#### **Comparator(s)**

The application proposed that the appropriate comparator for the proposed intervention is OMT alone, as patients with severe, symptomatic TR are generally managed with medical therapy due to their ineligibility for surgery.

Medical therapy for TR typically involves increasing doses of medications aimed at reducing congestion, alleviating volume overload, and managing heart failure symptoms. Current guidelines recommend diuretics as the cornerstone of medical management, particularly to relieve symptoms of right-sided heart failure, such as peripheral oedema and ascites (Otto et al. 2021; Vahanian et al. 2022). In some cases, treatment may also address pulmonary arterial hypertension. Patients with right heart dilation due to pulmonary embolism usually receive anticoagulation therapy, either with a direct-acting anticoagulant or warfarin. If atrial fibrillation is present, anticoagulants and other pharmacological interventions may be used to restore normal sinus rhythm. However, the effectiveness of medical therapy is limited in many patients due to comorbidities like impaired kidney function, which restrict the types and doses of medications that can be used. Importantly, while medical therapy can improve TR by adjusting volume status and promoting atrial/ventricular remodelling, it cannot directly reverse the condition and has no morbidity or mortality benefit in TR (Davidson et al. 2024; Messika-Zeitoun et al. 2020).

<sup>3</sup> Discussed at the Pre-PASC meeting with the applicant on 27 February 2025.

OMT was also used as the comparator in the TRISCEND II Pivotal Trial, which included patients with severe, symptomatic TR despite being on stable oral diuretic therapy (primarily the loop diuretic furosemide). The trial also allowed entry for patients who had a documented intolerance to diuretics; however, the exact number of participants enrolled based on this criterion was not disclosed in the study publications (Arnold et al. 2025; Hahn et al. 2025).

The healthcare resources used to deliver OMT include ongoing consultations with cardiologists and other specialists. Patients receiving OMT (including those who continue OMT after TTVR) require ongoing monitoring of weight, blood pressure, symptoms, renal function and electrolytes.

The intervention (TTVR in addition to continued OMT) will likely displace some use of OMT alone. A multinational, retrospective analysis of patients who received the EVOQUE system under compassionate use between 2019 and 2021 found a reduction in the dosage of loop diuretics following EVOQUE device implantation, with this reduction being sustained during follow up (Stolz et al. 2023).

An alternative comparator not mentioned in the application is TTV repair. While two TTV repair devices—the PASCAL System and the TriClip System—are registered for use in Australia, there are no relevant MBS items for TTV repair, nor have there been any MSAC applications for the use of these devices in TTV repair. Additionally, due to the novelty of TTVI technology, there is currently no direct comparative evidence of TTVR versus TTV repair.

*PASC agreed that OMT alone is the appropriate comparator, noting that patients with severe, symptomatic TR have limited therapeutic options and medical therapy is largely limited to diuretics and possibly also sodium-glucose cotransporter-2 (SGLT2) inhibitors.*

*PASC acknowledged that isolated tricuspid valve surgery could be an option for a small subset of the proposed population but due to the morbidity and mortality risk associated with surgery and the uncertainty in outcomes achieved, surgery is infrequently offered in this population. PASC therefore considered surgery to not be an appropriate comparator to TTVR.*

*PASC agreed that TTV repair is not an appropriate comparator because it was unlikely to be replaced in clinical practice, having only recently been adopted in Australia. Additionally, PASC noted advice from the applicant's clinical experts that the anatomy and pathology of patients who would undergo TTV repair differ from those who would receive TTVR.*

## Outcomes

The outcomes relevant to the assessment of TTVR are summarised in Table 5.

**Table 5 Outcomes relevant to the assessment of TTVR**

Outcome type	Outcome
Safety	Major cardiovascular events (MI, stroke, cardiovascular death) Severe bleeding Major access site and vascular complications Major cardiac structural complications (e.g. coronary structure perforation) Arrhythmia or conduction disorder requiring permanent pacing New need for renal replacement therapy Conversion to surgery Tricuspid valve reintervention (percutaneous or surgical) Prosthetic valve dysfunction
Efficacy/effectiveness	Mortality (all cause, cardiovascular) Hospitalisation for heart failure Implantation of a RV assist device or heart transplantation Change in TR grade Quality of life using disease-specific tools (e.g. KCCQ) and generic tools (e.g. EQ-5D, SF-36) Health status (NYHA functional class, 6MWT) Change in medical therapy (dose, frequency, type)
Healthcare resources	Cost of tricuspid valve prosthesis and other consumables Cost to deliver TTVR intervention Cost associated with changes in clinical management (testing required before the procedure, length of hospital stay, post-discharge rehabilitation) Cost associated with management of complications (including reintervention)
Cost-effectiveness	Cost per life-year gained Cost per QALY gained
Total Australian government healthcare costs	Total cost to the MBS Total cost to other government health budgets, including the PBS

EQ-5D = EuroQol 5-dimension tool; KCCQ = Kansas City Cardiomyopathy Questionnaire; NYHA = New York Heart Association; MBS = Medical Benefits Schedule; MI = myocardial infarction; 6MWT = 6-minute walk test; PBS = Pharmaceutical Benefits Scheme; QALY = quality-adjusted life year; RV = right ventricular; SF-36 = Medical Outcomes Study 36-item Short Form Health Survey; TR = tricuspid regurgitation; TTVR = transcatheter tricuspid valve replacement

Patient-reported outcomes are important to demonstrate the effectiveness of TTVR given that the optimisation of a patient's health status (i.e. symptoms, functional status and quality of life) is a central goal in the treatment of severe TR.

Procedural and late safety events should be captured in the analysis as both must be factored into clinical decision making, especially given the advanced age of the population and need for anticoagulation.

Tricuspid valve reintervention may be related to an unsuccessful implantation procedure, device failure or device-related complication events, either acute (e.g. embolisation) or chronic (e.g. paravalvular leak).

All safety and efficacy outcomes in Table 5 were captured in the TRISCEND II Pivotal Trial, with the exception of health-related quality of life (HRQOL) using generic tools such as the EuroQol 5-dimension

tool (EQ-5D) or the 36-item Short Form Health Survey (SF-36). The primary outcome measure for TRISCEND II was a hierarchical composite at 1 year that included:

- all-cause mortality
- durable implantation of an RV assist device or heart transplantation
- tricuspid-valve surgery or percutaneous tricuspid intervention after any index intervention
- heart failure hospitalisation
- health status measured using the Kansas City Cardiomyopathy Questionnaire overall summary (KCCQ-OS)
- NYHA functional class
- 6-minute walk test (6MWT).

The application stated that the individual components of the composite are available for inclusion in the assessment report; however, the trial was not powered or designed to detect differences in the individual components.

*PASC agreed that the proposed outcomes are appropriate and are consistent with those in the TRISCEND II Pivotal Trial. PASC discussed the hierarchical primary outcome, noting the analysis was presented as a win ratio using an unmatched pairs approach. PASC acknowledged that this approach may overcome some of the limitations of traditional composite endpoints by including a specific hierarchy of importance for each clinical endpoint, prioritising those considered more important such as death or heart transplant. PASC noted the trial was not powered to detect differences in secondary outcomes, including individual components of the composite.*

The Tricuspid Valve Academic Research Consortium (TVARC) advise that the duration of follow up must be sufficient to ascertain whether device durability is acceptable for the intended patient population and comparable to alternative therapies (Hahn et al. 2023). The TRISCEND II Pivotal Trial will follow up study participants to 5 years, with estimated study completion in December 2029. The application stated that published follow up is available for safety and efficacy outcomes to 1 year. The applicant confirmed that 2-year data have been presented at an international conference.<sup>4</sup>

*PASC noted that the applicant advised that further outcome data including beyond 12 months is expected to become available and may be presented in the assessment.*

## Clinical management algorithms

The current clinical management algorithm for patients with severe, symptomatic TR despite OMT is shown in Figure 1. Patients receive testing to determine TR aetiology, severity and suitability for surgery. Key tests and resources include:

- initial clinical evaluation
  - assessment by a GP to review medical history for conditions associated with TR, including heart failure and other comorbidities
- diagnostic imaging
  - TTE is the primary imaging modality to evaluate valve structure and TR severity

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<sup>4</sup> Discussed at the Pre-PASC meeting with the applicant on 27 February 2025.

- TOE provides detailed images, particularly when TTE results are inconclusive
- CT scan is required to assess the anatomy and suitability of the tricuspid valve area
- multidisciplinary heart team assessment
  - evaluation by a team consisting of an interventional cardiologist, a cardiac imaging specialist, and potentially a cardiothoracic surgeon, that assess the patient's overall risk, anatomy, and suitability for further intervention.

Several surgical risk assessment tools are available, such as the EuroSCORE, the Society of Thoracic Surgeons (STS) Risk Score, and the TRI-SCORE scoring system, which is a newer risk score for in-hospital mortality prediction following isolated TV surgery, based on a large multicentre database (Gröger et al. 2023).

*PASC noted that patients who may be surgical candidates may decline it, or not be offered it due to surgeon reluctance, given the high morbidity and mortality associated with isolated tricuspid valve surgical intervention and concerns around the reliability of surgical risk prediction tools in this patient cohort.*

Without the proposed health technology, patients with severe, symptomatic TR may be considered, on the basis of clinical and technical factors, for TTV repair. The PASCAL Precision System and the TriClip Transcatheter Tricuspid Valve Repair System are commercially available in Australia for this purpose but uptake of the technology in the private setting is limited (hence the perforated arrows in Figure 1).

*PASC noted that TTV repair is currently undertaken at public hospitals but not at private hospitals because the procedure is not listed on the MBS nor are the devices funded for this indication on the PL. For that reason, PASC questioned whether TTV repair should be included in the clinical management algorithms. However, PASC were advised by the applicant's clinical expert that TTV repair is currently being undertaken in the public setting in Australia and to a limited extent in the private setting. PASC noted that the optimal TTVI approach would be determined by the multidisciplinary heart team on a case-by-case basis; some patients may be more suited to one technique than the other.*

The 2021 ESC/EACTS algorithm for the management of TR (Figure 8, p.598 of the published guidelines) shows TTVI as an option for patients with severe, symptomatic secondary TR but the guidelines remain silent on it as an option for patients with primary TR. The applicant's clinical expert advised that the European guidance is likely to evolve in future updates of the guidelines to reflect more recent evidence for the use of TTVI in patients with severe, symptomatic primary or secondary TR.<sup>5</sup>

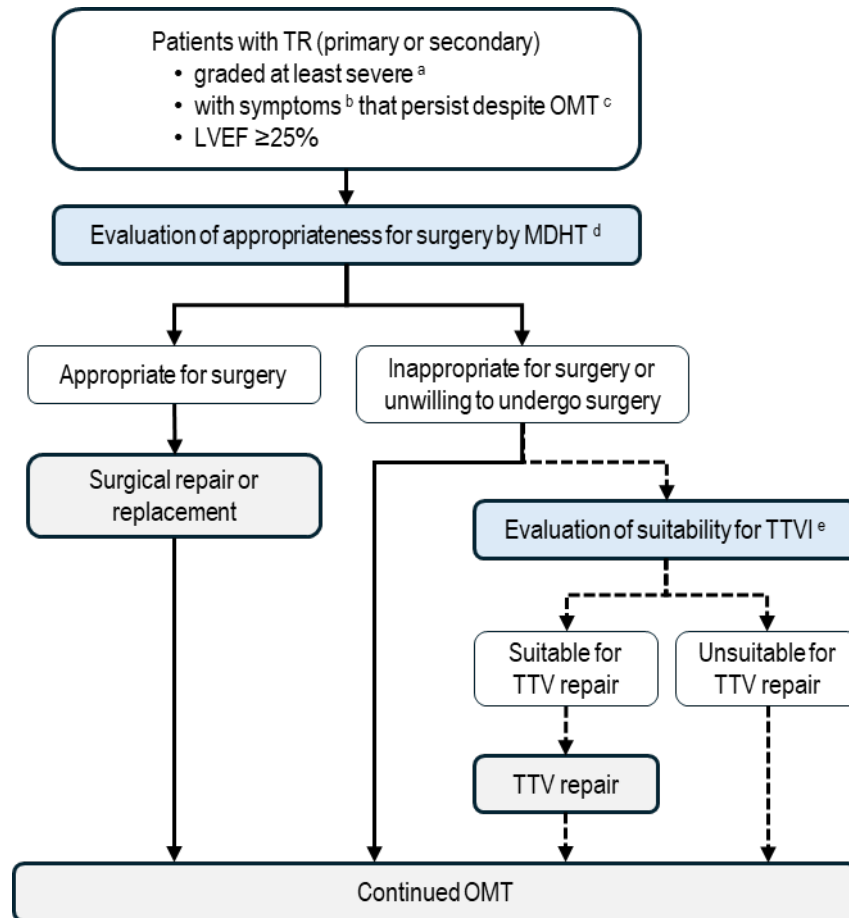
If TTV repair is undertaken, patients continue OMT, with adjustments to medications and/or doses as determined by their treating physician.

Patients who are considered unsuitable for surgery or TTV repair remain on OMT and typically require ongoing monitoring of weight, blood pressure and symptom exacerbation, alongside full blood tests for renal function and electrolytes.

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<sup>5</sup> Discussed at the Pre-PASC meeting with the applicant on 27 February 2025.

**Figure 1 Clinical management algorithm for patients with severe TR: current practice without TTVR**



Source: Prepared by the assessment group.

LVEF = left ventricular ejection fraction; MDHT = multidisciplinary heart team; NYHA = New York Heart Association; OMT = optimal medical therapy; TR = tricuspid regurgitation; TTV = transcatheter tricuspid valve; TTVI = transcatheter tricuspid valve intervention.

Note: Perforated arrow indicates limited uptake of intervention in the private setting.

a Severity determined by echocardiography using American Society of Echocardiography (ASE) grading.

b Symptomatic = NYHA functional class II or greater.

c OMT refers to stable oral diuretic therapy at a minimum.

d Patients are considered for surgery by a multidisciplinary heart team, combining surgical risk assessment, frailty, major organ dysfunction and procedure-specific impediments.

e Patients are considered for TTV repair based on clinical and technical factors.

The proposed clinical management algorithm – with TTVR– is shown in Figure 2.

The application claimed that resource utilisation *prior* to the use of TTVR will be the same for the current and proposed clinical management algorithms.

With the proposed health technology, patients with severe, symptomatic TR will be assessed for suitability for a transcatheter intervention by a multidisciplinary heart team. The heart team determines whether the patient is appropriate for surgery or suitable for TTVR or TTV repair based on an assessment of clinical and technical factors. TTVR is only an option for patients who can access a heart centre that is accredited for provision of TTVR, with specialists that are appropriately trained and accredited to perform the procedure.

As mentioned earlier, uptake of TTV repair in the private setting is currently limited (hence the perforated arrows in Figure 2). However, TTV repair may be a preferable option when TTVR is not feasible due to poor RV function, which remains the primary limiting factor for valve replacement. Additionally, the long-term



risk of bleeding is an important consideration. Patients at high risk who cannot tolerate lifelong anticoagulation, which is required for currently available replacement devices, may be better candidates for TTV repair (Rahgozar et al. 2021).

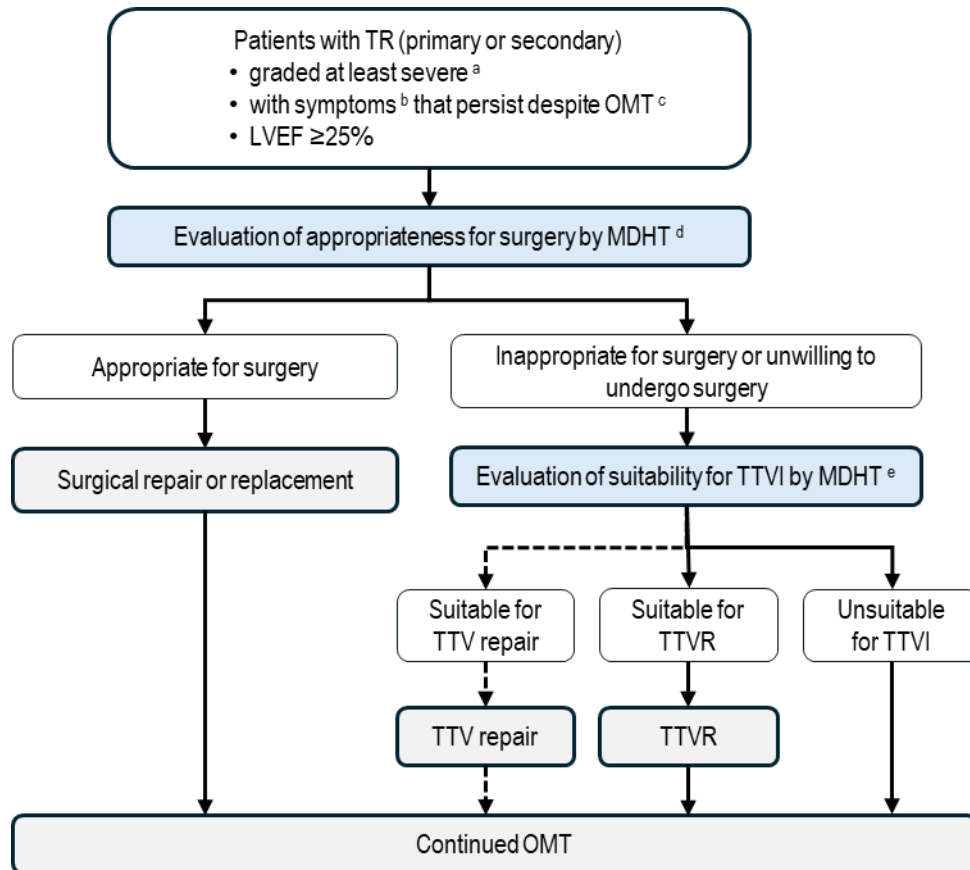
Tricuspid valve replacement may be the only transcatheter option in cases where valve leaflets are of inadequate length or are severely calcified, fibrotic, degenerated or retracted making it difficult for coaptation devices to securely grasp the leaflets. Likewise, grasping leaflets during transcatheter edge-to-edge repair is challenging if tricuspid valve annuli are severely dilated, coaptation gaps are large, or leads from pacemakers or implantable cardioverter defibrillators traverse the tricuspid valve (Nagraj et al. 2022).

Another potential advantage of valve replacement is its ability to completely eliminate TR, whereas TTV repair generally only reduces its severity. Additionally, implanting a bioprosthetic valve in the tricuspid annulus allows for the possibility of future valve-in-valve interventions if needed after the initial procedure (Rahgozar et al. 2021). Several case reports have documented successful transcatheter tricuspid valve-in-valve (TTViV) procedures using the Edwards SAPIEN valve, leading to symptomatic relief and improved functional status in patients with failing tricuspid bioprosthesis (Schaefer et al. 2016; Loyalka et al. 2017; Mortazavi et al. 2014).

All patients with severe functional TR should be medically optimised prior to consideration for TTVI (Rahgozar et al. 2021). Volume management through diuretic therapy, pharmacological neurohormonal blockade, and rate control (along with rhythm control in select patients) should be optimised to the highest tolerated level. A thorough evaluation of the patient's overall health and functional status is essential. For patients with a life expectancy of less than one year or those with extreme frailty, medical therapy should remain the primary approach, as data on the clinical benefits of TTVI in this population are limited (Rahgozar et al. 2021).

After TTVI (TTVR or TTV repair), patients will continue treatment with OMT, with adjustments to medications and/or doses as determined by their treating physician.

**Figure 2 Clinical management algorithm for patients with severe TR: proposed practice with TTVR**



Source: Prepared by the assessment group.

LVEF = left ventricular ejection fraction; MDHT = multidisciplinary heart team; NYHA = New York Heart Association; OMT = optimal medical therapy; TR = tricuspid regurgitation; TTV = transcatheter tricuspid valve; TTVI = transcatheter tricuspid valve intervention; TTVR = transcatheter tricuspid valve replacement.

Note: Perforated arrow indicates limited uptake of intervention in the private setting.

a Severity determined by echocardiography using American Society of Echocardiography (ASE) grading.

b Symptomatic = NYHA functional class II or greater.

c OMT refers to stable oral diuretic therapy at a minimum.

d Patients are considered for surgery by a multidisciplinary heart team, combining surgical risk assessment, frailty, major organ dysfunction and procedure-specific impediments.

e Patients are considered for TTVI by a multidisciplinary heart team based on a detailed assessment of comorbidities and expected benefits. The decision between replacement or repair is dependent on clinical and technical factors.

The differences in healthcare resources used *after* the proposed versus current treatment options are:

- monitoring and follow up
  - TTVR demands structured, frequent follow ups with regular imaging to assess valve function, whereas OMT requires periodic follow ups focused on fluid status and symptom management
- anticoagulation
  - TTVR patients need long-term anticoagulation, increasing medication management and monitoring needs, unlike OMT where anticoagulation is not routine
- electrocardiographic monitoring
  - continuous ECG monitoring post-TTVR is common to detect conduction issues, while OMT generally doesn't require continuous ECG

- ongoing monitoring of weight, blood pressure, symptoms, renal function and electrolytes would occur after both the proposed and comparator technologies.

## Proposed economic evaluation

Based on the application's clinical claims of **superior efficacy** (in terms of health status) and **non-inferior safety** (in terms of long-term adverse events), a cost-utility analysis (CUA) is appropriate (Table 6).

The key evidence cited in the application to support the clinical claims is the TRISCEND II Pivotal Trial. Eligible patients were randomised 2:1 into two groups: EVOQUE system plus OMT (N=267) versus OMT alone (N=133). The trial was designed to have two primary analysis phases: health status evaluation of 150 patients at 6 months ('Breakthrough Pathway Cohort') and an assessment of morbidity/mortality on the full 400 enrolled patients at 1 year ('Full Cohort'). Long-term follow-up data beyond 2 years may not be available.

**Table 6 Classification of comparative effectiveness and safety of the proposed intervention, compared with its main comparator, and guide to the suitable type of economic evaluation**

Comparative safety-	Comparative effectiveness			
	Inferior	Uncertain <sup>a</sup>	Noninferior <sup>b</sup>	Superior
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain <sup>a</sup>	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior <sup>b</sup>	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

CEA=cost-effectiveness analysis; CMA=cost-minimisation analysis; CUA=cost-utility analysis.

? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis.

<sup>a</sup> 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations.

<sup>b</sup> An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence.

TTVR is expected to be more costly than OMT alone because of the additional costs for the medical procedure, skilled surgical staff, specialised equipment, operating room time, and long-term monitoring and anticoagulation. OMT alone incurs no costs from procedure-related complications, hospital stays, or recovery periods and rehabilitation, making it inherently less expensive.

The application stated that the overall cost per patient of providing TTVR using the EVOQUE system is approximately \$REDACT:

- device cost (Edwards EVOQUE valve, delivery system, dilator kit and loading system) \$REDACT
- proposed MBS fee \$1,631.65 – \$1,800
- other costs, including hospitalisation \$61,569.<sup>6</sup>

<sup>6</sup> Based on weighting of Diagnosis Related Group (DRG) F21A and F21B. The application notes that DRG F25 may also be applicable to the TTVR procedure.

*PASC agreed that a CUA is appropriate for the clinical claims of superior efficacy and non-inferior safety. However, PASC noted the clinical evidence presented was restricted to a single trial with a relatively high incidence of adverse events compared to other heart valve trials. PASC discussed whether TTVR safety could be considered inferior to OMT, noting the high incidence of early death (3.5%), severe bleeding (10%) and requirement for pacing (15%) in TRISCEND II. PASC noted advice from the applicant's clinical experts that the results of TRISCEND II reflect early experience with the device and there have been significant learnings in terms of management of bleeding complications.*

*PASC suggested inclusion of post-market registry data would be useful to support the safety of the TTVR procedure and demonstrate the reduction in complication rates that is expected in real-world settings. PASC were advised by the applicant's clinical experts of the TVT registry in the USA, mandated by the FDA, that monitors real-world outcomes related to transcatheter valve therapies, and a newly established independent, investigator-driven registry in Australia, sponsored by Queensland Health, that will collect TTVI outcomes.*

*PASC considered that it may be challenging to demonstrate cost-effectiveness based on the results from the TRISCEND II Pivotal Trial and the relatively high cost of the device, which is more than twice the cost of the TAVI valve.*

## **Proposal for public funding**

The application proposed the creation of a new MBS item for isolated TTVR performed using the EVOQUE tricuspid valve replacement system (Table 7). The rationale in the application for specifying the EVOQUE system is that no other TTVR devices are currently included in the ARTG, and EVOQUE is currently the only device with RCT evidence.

*PASC noted that consistent with current departmental policy, device-agnostic items were preferred in terms of future proofing any ensuing MBS listing. However, PASC advised the applicant that the ADAR would need to provide justification and evidence to support the case for a device-specific MBS listing for MSAC consideration.*

The proposed MBS item descriptor specifies that the service is to be performed via a transfemoral venous approach. In response to a query about this from the department, the applicant's clinical expert advised that the EVOQUE valve is designed to be implanted using transfemoral access, but the MBS item descriptor need not specify this approach.<sup>7</sup> Although the transfemoral approach is common across several TTVR devices in development, some rely on transatrial access (see Table 2).

Notably, the proposed descriptor specifies replacement of the tricuspid valve; it does not include TTV repair. The application explained that TTVR and TTV repair should not be considered interchangeable. Clinical and technical factors are taken into consideration by the heart team when choosing the most appropriate TTVI for a particular patient. Furthermore, previous studies evaluating TTV repair technologies have shown these devices to be safe and effective, however they frequently leave clinically significant levels of residual regurgitation, which is associated with worse long-term outcomes (Hahn et al. 2025).

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<sup>7</sup> Discussed at the Pre-PASC meeting with the applicant on 27 February 2025.

While TTV repair devices are commercially available in Australia, there are currently no MBS items for the procedure.

Similar to the MBS items for TMVr (MBS items 38461 and 38463), the proposed descriptor for the new TTVR item includes intraoperative diagnostic imaging to cover fluoroscopy and TOE used throughout the procedure to guide implantation, as well as TOE to confirm proper positioning and functioning of the artificial valve.

The population proposed in the item descriptor is broadly consistent with the population from the TRISCEND II Pivotal Trial. The definition of OMT is not defined in the descriptor, but according to best practice it would likely include stable oral diuretic medications at a minimum (unless the patient had a documented history of intolerance). The proposed descriptor does not specify notable trial exclusion criteria (such as age <18 years; anatomy precluding proper device implantation; evidence of severe RV dysfunction; severe renal insufficiency; severe pulmonary hypertension; severe aortic, mitral or pulmonic valve stenosis or regurgitation). However, the application noted that these factors would be taken into consideration by the multidisciplinary heart team who are required to determine suitability for TTVR.

The application advised that the multidisciplinary heart team should include at least an interventional cardiologist or cardiothoracic surgeon, an imaging cardiologist who is trained on TOE imaging, and an anaesthesiologist. The assessment group noted that new MBS items would be required for attendance at a TTVR suitability case conference, akin to MBS items 6080, 6081, 6082 and 6084 for TMVr and TAVI case conferences.

*PASC considered the composition of the multidisciplinary heart team, including whether the interventional cardiologist or cardiothoracic surgeon who performs the procedure (and therefore financially benefits) should be involved in determining patient suitability for TTVR. PASC agreed with advice from the department that the team composition should follow the same as for TAVI/TMVr.*

The proposed item descriptor requires that interventional cardiologists and cardiothoracic surgeons who perform TTVR are trained and certified by the TTVR accreditation committee, which also provides accreditation for hospitals that perform the procedure. Services relating to TAVI and TMVr have similar requirements, with formal recognition provided by specialised TAVI and TMVr accreditation committees appointed by Cardiac Accreditation Services Ltd. These committees comprise cardiologists and cardiothoracic surgeons nominated by the Cardiac Society of Australia and New Zealand (CSANZ) and the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS). The applicant has indicated a willingness to work alongside key opinion leaders, including the relevant societies, in consultation with government and consumers, to ensure that robust accreditation measures and processes are put in place before implantation with the EVOQUE system begins.<sup>7</sup>

The MBS item descriptor proposed in the application does not restrict the service to standalone/independent TTVR procedures. However, the applicant confirmed that TTVR is intended to be performed for isolated TR, not in conjunction with other minimally invasive or transvenous interventions such as TMVr.

The service is intended to be performed only once per lifetime, hence criterion (d) in the proposed item descriptor (see Table 7), which restricts the service to patients who have not previously undergone TTVR. The exclusion criteria in the TRISCEND II Pivotal Trial were broader than this, extending to patients with

any prior history of tricuspid surgery or intervention. The applicant clarified there is now real-world experience, albeit limited, for the use of the EVOQUE system in patients who have undergone previous tricuspid valve repair at the time of open-heart surgery. The applicant's clinical expert advised that further evidence may emerge for the safety and effectiveness of the EVOQUE system in this niche patient population, particularly in cases of failed mitral valve repair, and it may be prudent not to exclude these patients from access to TTVR.<sup>7</sup>

The durability of the EVOQUE valve has been demonstrated through bench testing, 2-year follow up in clinical trials, and inference from longer-term (5-year) experience with comparable transcatheter bioprosthetic valves implanted on the left and right side. There are no existing MBS items for transcatheter repair or replacement of a dysfunctional prosthetic tricuspid valve. Although there are reports of transcatheter devices being used for repair or valve-in-valve replacement of dysfunctional bioprosthetic tricuspid valves, use of such devices for this purpose would currently be off-label in Australia.

*PASC agreed that the limit of one TTVR procedure per lifetime is reasonable. PASC noted that the patient population is elderly and unlikely to outlive the bioprosthetic valve; however, a valve-in-valve intervention might be possible in the future.*

*PASC noted a small risk of early dislodgement of the bioprosthetic valve, which would require surgical removal, but were advised that overt dislodgement is rare and was not seen in the clinical trial.*

**Table 7 New MBS item descriptor proposed by the application**

Category 3 – THERAPEUTIC PROCEDURES
<p>MBS item XXXXX</p> <p>Transcatheter tricuspid valve replacement using the EVOQUE tricuspid valve replacement system, including intraoperative diagnostic imaging if:</p> <p>(a) The patient has each of the following risk factors:</p> <ul style="list-style-type: none"> <li>(i) symptomatic, severe, or greater TR that has not responded adequately to OMT, defined as grade 3+;</li> <li>(ii) left ventricular ejection fraction of 25% or more.</li> </ul> <p>(b) The patient is deemed suitable for TTVR by a qualified multidisciplinary heart team, following a detailed assessment of comorbidities and expected benefits.</p> <p>(c) The Service is performed:</p> <ul style="list-style-type: none"> <li>(i) by an accredited interventional cardiologist or cardiothoracic surgeon trained and certified by the TTVR Accreditation Committee.</li> <li>(ii) via transfemoral venous approach.</li> <li>(iii) in a hospital accredited by the TTVR Accreditation Committee to ensure appropriate facilities, personnel, and postoperative care.</li> </ul> <p>(d) a service to which this item applies, or any other item covering TTVR, must not have been provided to the patient before.</p> <p>(H) (Anaes.) (Assist.)</p>
<p>Fee: \$1,631.65 Benefit: 75% = \$1,223.75</p>

The application stated that the proposed fee (\$1,631.65 to \$1,800) is comparable to the existing fee for TMVr (\$1,631.65 in February 2025)<sup>8</sup> on the basis that the TTVR procedure will require a similar level of time, skill and training to provide. Although not mentioned in the application, a 75% benefit would be appropriate given the procedure is for hospital inpatients only.

*PASC considered that the proposed fee should be commensurate with that for TMVr.*

The assessment group proposed an alternative MBS item descriptor (Table 8) that captures advice from the applicant's clinical expert<sup>7</sup> and specifies appropriate measures to determine patients who are eligible for the service.

In addition, the assessment group proposed 2 new MBS items for attendance at TTVR case conferences (Table 9), based on MBS items 6082 and 6084 for attendance at TMVr case conferences.

**Table 8 New MBS item descriptor for TTVR supported by PASC**

Category 3 – THERAPEUTIC PROCEDURES
<p>MBS item XXXXX</p> <p>Transcatheter tricuspid valve replacement (TTVR) , including intraoperative diagnostic imaging if:</p> <p>(a) the patient has:</p> <ul style="list-style-type: none"> <li>(i) severe or greater tricuspid regurgitation, as determined by echocardiography;</li> <li>(ii) symptoms (New York Heart Association functional class II or greater) despite optimal medical therapy;</li> <li>(ii) left ventricular ejection fraction of 25% or more; and</li> </ul> <p>(b) the patient is deemed suitable for isolated TTVR by a qualified multidisciplinary heart team, following a detailed assessment of comorbidities and expected benefits; and</p> <p>(c) the service is performed:</p> <ul style="list-style-type: none"> <li>(i) by an accredited interventional cardiologist or cardiothoracic surgeon trained and certified by the TTVR accreditation committee;</li> <li>(ii) in a hospital accredited by the TTVR accreditation committee to ensure appropriate facilities, personnel, and postoperative care; and</li> </ul> <p>(d) the service is not associated with a service to which item 38516, 38517 applies</p> <p>Applicable once per lifetime (H)</p> <p><a href="#">Multiple Operation Rule</a></p> <p>(Anaes.) (Assist.)</p> <hr/> <p>Fee: \$1,631.65Benefit: 75% = \$1,223.75</p>

<sup>8</sup> MBS items 38461 (TMVr by transvenous or transeptal techniques using 1 or more tissue approximation implants) and 38463 (TMVr by transvenous or transeptal techniques using 1 or more Mitraclip).

**Table 9 New MBS item descriptors for TTVR case conferences supported by PASC**

<b>Category 1 – PROFESSIONAL ATTENDANCES</b>
<p>MBS item YYYY</p> <p>Attendance at a TTVR suitability case conference, by a cardiothoracic surgeon or an interventional cardiologist, to coordinate the conference, if:</p> <p>(a) the attendance lasts at least 10 minutes; and</p> <p>(b) the surgeon or cardiologist is accredited by the TTVR accreditation committee to perform the service</p> <p>Applicable once per patient per lifetime</p>
<p>Fee: \$58.00 Benefit: 75% = \$43.50 85% = \$49.30</p> <p><a href="#">Extended Medicare Safety Net Cap</a>: \$174.00</p>
<p>MBS item ZZZZ</p> <p>Attendance at a TTVR suitability case conference, by a specialist or consultant physician, other than to coordinate the conference, if the attendance lasts at least 10 minutes</p> <p>Applicable once per patient per lifetime</p>
<p>Fee: \$43.25 Benefit: 75% = \$32.45 85% = \$36.80</p> <p><a href="#">Extended Medicare Safety Net Cap</a>: \$129.75</p>

## Summary of public consultation input

*PASC noted and welcomed consultation input from 3 organisations and no individuals. The 3 organisations that submitted input were:*

- Hearts4heart
- Medtronic Inc.
- Private Healthcare Australia (PHA)

The consultation input varied from supportive to not supportive of public funding for TTVR in patients with severe, symptomatic tricuspid regurgitation despite optimal medical therapy. The consultation input raised a number of concerns, predominately in relation to the proposed item descriptor and the overall cost for the health service or technology.

### Benefits and Disadvantages

The main benefits of public funding received in the consultation input included providing a treatment option for patients who are not candidates for traditional surgery, improving the health and quality of life for patients. Hearts4heart stated that compared with OMT alone, treatment of patients with TTVR plus OMT resulted in substantial improvement in patients' symptoms, function, and quality of life, with the benefits continuing for a year.

The main disadvantage of public funding received in the consultation input was the high cost associated with the intervention. PHA estimated that the total cost would be more than \$125,000 for the intervention, compared to almost zero-cost diuretics under optimal medical therapy.



## **Population, Comparator (current management) and Delivery**

The consultation input agreed with the proposed population of patients with severe, symptomatic TR despite optimal medical therapy.

The consultation input agreed with the proposed comparator of optimal medical management.

Services identified in the consultation input as being needed to be delivered before or after the intervention included the services required to deliver the intervention in hospital and the associated hospital stay.

## **MBS Item Descriptor and Fee**

The consultation input from PHA and Medtronic disagreed with the proposed service descriptor. Medtronic recommended amending the proposed MBS item descriptor to remove reference to a specific device, using a device-agnostic approach. PHA noted that the item descriptor covers metrics that are not going to be visible to insured members or health funds, so MBS item use would largely be based on trust.

The consultation input ranged from agreeing to disagreeing with the proposed service fee. Medtronic stated that the proposed MBS fee is appropriate as it is based on the existing fee for transcatheter mitral valve repair. PHA disagree with the proposed fee stating that the MBS fee does not represent the cost of the intervention as the surgeon's fee is a comparatively small amount of the real intervention cost.

## **Additional Comments**

Consultation input was provided on the outcomes, which PHA stated should be reported consistent with the TRISCEND and TRISCEND II data. PHA accepted there were modest improved outcomes across a number of measures, but noted there was also an increase in immediate post-surgery mortality. PHA stated the population are both aged and have other comorbidities that influence any long-term outcomes, noting that the small number of members who may benefit from this surgery are massively overrepresented by the remainder of private health insured members who would potentially incur a substantial increase in annual premiums to fund this intervention.

*PASC noted that public consultation feedback from Hearts 4 Heart was strongly supportive of the proposal. Feedback from Medtronic was also supportive but a device-agnostic listing was requested. PASC noted that Private Healthcare Australia (PHA) agreed with the PICO components but suggested that the intervention will not be cost effective due to the high cost of the valve and implant procedure, and the limited clinical evidence of efficacy.*

## **Next steps**

*The applicant confirmed that an applicant developed assessment report (ADAR) will be prepared.*

## **Applicant Comments on Ratified PICO**

Edwards appreciates the opportunity to provide feedback on the proposed MBS item descriptor for TTVR. We accept the proposed device agnostic MBS item descriptor as per the PASC in Table 8.

As a principle, we acknowledge that MBS item descriptors have traditionally been device-agnostic to promote neutrality and support competition. However, precedent has been set where device specific names have been included in item descriptors. The most relevant example is the inclusion of “MitraClip” in the original MBS item for transcatheter edge-to-edge repair (TEER) of the mitral valve.

This device specific approach has created ongoing administrative and procedural complexity. When competitor products entered the market—specifically the PASCAL system—we were required to submit multiple applications to MSAC to amend the existing MBS item. Despite these efforts, the MBS item for functional mitral regurgitation (FMR) remains device specific, while only degenerative MR has been transitioned to a device agnostic item.

By accepting the PASC recommended MBS item descriptor in Table 8 Edwards is seeking a return to a consistent policy approach, despite EVOQUE being the only TTVR with RCT data. Inconsistent application of device agnostic MBS item policy risks creating competitive disadvantage and perpetuates unnecessary administrative burden through repeated MSAC applications.

## References

- Arnold SV, Hahn RT, Thourani VH, Makkar R, Makar M, Sharma RP, Haeffele C, Davidson CJ, Narang A, O'Neill B, Lee J, Yadav P, Zahr F, Chadderdon S, Eleid M, Pislaru S, Smith R, Szerlip M, Whisenant B, Sekaran N, Garcia S, Stewart-Dehner T, Grayburn PA, Sannino A, Snyder C, Zhang Y, Mack MJ, Leon MB, Lurz P, Kodali S, Cohen DJ; TRISCEND II Pivotal Trial Investigators (2025) 'Quality of life after transcatheter tricuspid valve replacement: 1-year results from TRISCEND II Pivotal Trial', *J Am Coll Cardiol*, 85(3):206-216, doi: 10.1016/j.jacc.2024.10.067.
- Cahill TJ, Prothero A, Wilson J, Kennedy A, Brubert J, Masters M, Newton JD, Dawkins S, Enriquez-Sarano M, Prendergast BD and Myerson SG (2021) 'Community prevalence, mechanisms and outcome of mitral or tricuspid regurgitation', *Heart*, 107(12):1003-1009, doi: 10.1136/heartjnl-2020-318482.
- Chorin E, Rozenbaum Z, Topilsky Y, Konigstein M, Ziv-Baran T, Richert E, Keren G and Banai S (2020) 'Tricuspid regurgitation and long-term clinical outcomes', *Eur Heart J Cardiovasc Imaging*, 21(2):157-165, doi: 10.1093/ehjci/jez216.
- Davidson LJ, Tang GHL, Ho EC, Fudim M, Frisoli T, Camaj A, Bowers MT, Masri SC, Atluri P, Chikwe J, Mason PJ, Kovacic JC, Dangas GD; American Heart Association Interventional Committee of the Council on Clinical Cardiology; Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation; Council on Cardiovascular Surgery and Anesthesia; and Council on Cardiovascular and Stroke Nursing (2024) 'The tricuspid valve: A review of pathology, imaging, and current treatment options: A Scientific Statement from the American Heart Association', *Circulation*, 149(22):e1223-e1238, doi: 10.1161/CIR.0000000000001232.
- Fujisawa T, Kimura T, Ikemura N, Miyama H, Katsumata Y, Ueda I, Tanimoto K, Kanki H, Fukuda K, Kohsaka S and Takatsuki S (2022) 'Effect of tricuspid regurgitation on the reported quality of life and subsequent outcomes in patients with atrial fibrillation', *J Am Heart Assoc*, 11(8):e022713, doi: 10.1161/JAHA.121.022713.
- Grayburn PA, Kodali SK, Hahn RT, Lurz P, Thourani VH, Kozorovitsky ER, Gilmore SY, Vinekar C, Zhang B, Boulware K, Krzmarzick AM, Nguyen D, Vu MT, Feldman T, Mack MJ and Leon MB (2024) 'TRISCEND II: Novel randomized trial design for transcatheter tricuspid valve replacement', *Am J Cardiol*, 225:171-177, doi: 10.1016/j.amjcard.2024.06.009.
- Gröger M, Friedl S, Ouerghemmi D, Tadic M, Bruß E, Felbel D, Paukovitsch M, Schneider LM, Dahme T, Rottbauer W, Markovic S and Keßler M (2023) 'TRI SCORE is superior to EuroSCORE II and STS-Score in mortality prediction following transcatheter edge-to-edge tricuspid valve repair', *Clin Res Cardiol*, 112(10):1436-45, doi: 10.1007/s00392-023-02246-9.
- Hahn RT, Lawlor MK, Davidson CJ, Badhwar V, Sannino A, Spitzer E, Lurz P, Lindman BR, Topilsky Y, Baron SJ, Chadderdon S, Khalique OK, Tang GHL, Taramasso M, Grayburn PA, Badano L, Leipsic J, Lindenfeld J, Windecker S, Vemulapalli S, Redfors B, Alu MC, Cohen DJ, Rodés-Cabau J, Ailawadi G, Mack M, Ben-Yehuda O, Leon MB and Hausleiter J (2023) 'Tricuspid Valve Academic Research Consortium definitions for tricuspid regurgitation and trial endpoints', *Eur Heart J*, 44(43):4508-4532, doi: 10.1093/eurheartj/ehad653.

Hahn RT, Makkar R, Thourani VH, Makar M, Sharma RP, Haeffele C, Davidson CJ, Narang A, O'Neill B, Lee J, Yadav P, Zahr F, Chadderdon S, Eleid M, Pislaru S, Smith R, Szerlip M, Whisenant B, Sekaran NK, Garcia S, Stewart-Dehner T, Thiele H, Kipperman R, Koulogiannis K, Lim DS, Fowler D, Kapadia S, Harb SC, Grayburn PA, Sannino A, Mack MJ, Leon MB, Lurz P, Kodali SK; TRISCEND II Trial Investigators (2025) 'Transcatheter valve replacement in severe tricuspid regurgitation', *N Engl J Med*, 392(2):115-126, doi: 10.1056/NEJMoa2401918.

Kumar K, Byrne T, Simpson TF, Samhan A, Shah R, Rodriguez J, Wagner L, Chadderdon SM, Song HK, Golwala H and Zahr FE (2022) 'Clinical predictors of mortality and heart failure hospitalization in patients with severe tricuspid regurgitation', *Struct Heart*, 7(2):100130, doi: 10.1016/j.shj.2022.100130.

Latib A, Grigioni F and Hahn RT (2018) 'Tricuspid regurgitation: what is the real clinical impact and how often should it be treated?', *EuroIntervention*, 14(AB):AB101-AB111, doi: 10.4244/EIJ-D-18-00533.

Loyalka P, Nascimbene A, Metz B, Gregoric ID, Raman AS and Kar B (2017) 'Transcatheter tricuspid valve-in-valve replacement with an Edwards Sapien 3 Valve', *Tex Heart Inst J*, 44(3):209-213, doi: 10.14503/THIJ-15-5639.

Messika-Zeitoun D, Verta P, Gregson J, Pocock SJ, Boero I, Feldman TE, Abraham WT, Lindenfeld J, Bax J, Leon M and Enriquez-Sarano M (2020) 'Impact of tricuspid regurgitation on survival in patients with heart failure: a large electronic health record patient-level database analysis', *Eur J Heart Fail*, 22(10):1803-1813, doi: 10.1002/ejhf.1830.

Mortazavi A, Reul RM, Cannizzaro L and Dougherty KG (2014) 'Transvenous transcatheter valve-in-valve implantation after bioprosthetic tricuspid valve failure', *Tex Heart Inst J*, 41(5):507-10, doi: 10.14503/THIJ-14-4302.

Nagraj S, Goldberg YH, Scotti A, Ho E, Assafin M, Chau M and Latib A (2022) 'Transcatheter tricuspid valve replacement: A feasible solution to a real-world problem', *Rev Cardiovasc Med*, 23(5):163, doi: 10.31083/j.rcm2305163.

Offen S, Playford D, Strange G, Stewart S and Celermajer DS (2022) 'Adverse prognostic impact of even mild or moderate tricuspid regurgitation: Insights from the National Echocardiography Database of Australia', *J Am Soc Echocardiogr*, 35(8):810-817, doi: 10.1016/j.echo.2022.04.003.

Otto CM, Nishimura RA, Bonow RO, Carabello BA, Erwin JP 3rd, Gentile F, Jneid H, Krieger EV, Mack M, McLeod C, O'Gara PT, Rigolin VH, Sundt TM 3rd, Thompson A and Toly C (2021) '2020 ACC/AHA Guideline for the management of patients with valvular heart disease: Executive Summary: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines', *Circulation*, 143(5):e35-e71. doi: 10.1161/CIR.0000000000000932. Erratum in: (2021) *Circulation*, 143(5):e228, doi: 10.1161/CIR.0000000000000960. Erratum in: (2021) *Circulation*, 143(10):e784, doi: 10.1161/CIR.0000000000000966.

Rahgozar K, Bruoha S, Ho E, Goldberg Y, Chau M and Latib A (2021) 'Rediscovered and forgotten: Transcatheter interventions for the treatment of severe tricuspid valve regurgitation', *US Cardiol*, 15:e22, doi: 10.15420/usc.2021.06.

Schaefer A, Conradi L, Seiffert M, Lubos E, Blankenberg S, Reichenspurner H, Schaefer U and Treede H (2016) 'Valve-in-valve procedures in failing biological xenografts using a novel balloon-expandable device: Experience in aortic, mitral, and tricuspid positions', *Thorac Cardiovasc Surg*, 64(5):366-73, doi: 10.1055/s-0035-1558647.

Scott A, Kern J and Vreugdenburg T (2024) *Caval valve implantation for severe tricuspid regurgitation*, AIHTA Decision Support Documents No. 139, Vienna: Austrian Institute for Health Technology Assessment GmbH.

Seligman H, Vora AN, Haroian NQ, Puri R, Heng EL, Smith RD, Latib A, Makkar R, Sorajja P, Leon MB and Ahmad Y (2023) 'The current landscape of transcatheter tricuspid valve intervention', *J Soc Cardiovasc Angiogr Interv*, 2(6Part B):101201, doi: 10.1016/j.jscai.2023.101201.

Stolz L, Weckbach LT, Hahn RT, Chatfield AG, Fam NP, von Bardeleben RS, Davidson CJ, Grayburn PA, Zahr F and Hausleiter J (2023) '2-year outcomes following transcatheter tricuspid valve replacement using the EVOQUE System', *J Am Coll Cardiol*, 81(24):2374-2376, doi: 10.1016/j.jacc.2023.04.014.

Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S, Bauersachs J, Capodanno D, Conradi L, De Bonis M, De Paulis R, Delgado V, Freemantle N, Gilard M, Haugaa KH, Jeppsson A, Jüni P, Pierard L, Prendergast BD, Sádaba JR, Tribouilloy C, Wojakowski W; ESC/EACTS Scientific Document Group (2022) '2021 ESC/EACTS Guidelines for the management of valvular heart disease', *Eur Heart J*, 43(7):561-632, doi: 10.1093/eurheartj/ehab395. Erratum in: (2022) *Eur Heart J*, 43(21):2022, doi: 10.1093/eurheartj/ehac051.

Webb JG, Chuang AM, Meier D, von Bardeleben RS, Kodali SK, Smith RL, Hausleiter J, Ong G, Boone R, Ruf T, George I, Szerlip M, Näbauer M, Ali FM, Moss R, Kreidel F, Bapat V, Schnitzler K, Ye J, Wild M, Akodad M, Deva DP, Chatfield AG, Mack MJ, Grayburn PA, Peterson MD, Makkar R, Leon MB, Hahn RT and Fam NP (2022) 'Transcatheter tricuspid valve replacement with the EVOQUE System: 1-year outcomes of a multicenter, first-in-human experience', *JACC Cardiovasc Interv*, 15(5):481-491, doi: 10.1016/j.jcin.2022.01.280.

Zoghbi WA, Adams D, Bonow RO, Enriquez-Sarano M, Foster E, Grayburn PA, Hahn RT, Han Y, Hung J, Lang RM, Little SH, Shah DJ, Shernan S, Thavendiranathan P, Thomas JD and Weissman NJ (2017) 'Recommendations for noninvasive evaluation of native valvular regurgitation: A report from the American Society of Echocardiography developed in collaboration with the Society for Cardiovascular Magnetic Resonance', *J Am Soc Echocardiogr*, 30(4):303-371, doi: 10.1016/j.echo.2017.01.007.

Zoghbi WA, Jone PN, Chamsi-Pasha MA, Chen T, Collins KA, Desai MY, Grayburn P, Groves DW, Hahn RT, Little SH, Kruse E, Sanborn D, Shah SB, Sugeng L, Swaminathan M, Thaden J, Thavendiranathan P, Tsang W, Weir-McCall JR and Gill E (2024) 'Guidelines for the evaluation of prosthetic valve function with cardiovascular imaging: A report from the American Society of Echocardiography developed in collaboration with the Society for Cardiovascular Magnetic Resonance and the Society of Cardiovascular Computed Tomography', *J Am Soc Echocardiogr*, 37(1):2-63, doi: 10.1016/j.echo.2023.10.004.