MSAC Application 1799

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

PICO Set

Population

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

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 of TR 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).

As per the American College of Cardiology (ACC)/American Heart Association (AHA), TR is classified by leaflet pathology as primary (due to abnormal tricuspid valve leaflets) or secondary (due to presence of left-sided heart disease) (Otto, Nishimura et al. 2021). 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 (Hahn 2023). 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 (Zoghbi, Adams et al. 2017). This can be further expanded to include massive and torrential grades (Hahn and Zamorano 2017). In clinical practice, severe TR can be used as an umbrella term that includes severe, massive and torrential grades.

Untreated severe TR can progress to right ventricular failure, which impacts a patient's prognosis and symptoms usually include oedema, ascites, dyspnoea, chest and abdominal pain, and fatigue. The prevalence of ≥moderate TR is estimated to be 2.6% in adults ≥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 ≥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). In Australia, current treatment options for patients with TR include watchful waiting, medical therapy (such as diuretics), or surgical procedures to repair or replace the tricuspid valve. In the 2020 ACC/AHA guidelines on the management of patients with heart valve disease, conventional open-heart valve surgery is recommended only for highly selected patients with moderate or severe TR (Otto, Nishimura et al. 2021). 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, Grigioni et al. 2018, Vahanian, Beyersdorf et al. 2021). Research has revealed mortality after TR surgery is high, with early mortality rates ranging from 10% to 30%, leading many to forgo surgical treatment in favour of medication alone (Fender, Zack et al. 2018).

While most patients rely on medical therapy alone to treat the symptoms of TR, there remains no Class I recommendation for medication management in clinical guidelines. According to both the AHA/ACC and the ESC/EACTS guidelines for the management of heart valve disease, diuretics may be beneficial for patients with severe TR and signs of right-sided heart failure to decrease volume overload (Otto, Nishimura et al. 2021, Vahanian, Beyersdorf et al. 2021). Diuretics can improve or delay the onset of symptoms, but they do not have an established role in preventing or delaying TR progression (Latib, Grigioni et al. 2018). The AHA/ACC guidelines further note that medical therapies for the management of severe TR are limited (Otto, Nishimura et al. 2021).

The Edwards EVOQUE tricuspid valve replacement system (EVOQUE system) is designed to reduce and/or eliminate TR without the need for conventional open-heart surgery. The EVOQUE system is specifically designed for the improvement of health status in patients with severe or greater symptomatic TR who remain symptomatic despite optimal medical therapy (OMT) and in whom tricuspid valve replacement is deemed appropriate by a Heart Team. This group primarily consists of elderly patients, who represent a significant portion of the TR population, experiencing severe heart failure symptoms and substantial decline in quality of life.

Specify any characteristics of patients with, or suspected of having, the medical condition, who are proposed to be eligible for the proposed health technology, describing how a patient would be investigated, managed and referred within the Australian healthcare system in the lead up to being considered eligible for the technology:

The clinical evaluation typically begins with a review by the general practitioner of the patient's history for conditions associated with TR, including left-sided heart failure, rheumatic heart disease, permanent pacemaker, endocarditis, and carcinoid heart disease. Right heart failure can also be associated with TR. The clinical presentation involves exercise limitation, fatigue, and evidence of systemic venous congestion(BMJ Best Practice 2024). Additional signs and symptoms associated with right-sided heart failure include abdominal distension from ascites; liver pulsation due to advanced liver disease from chronic congestion or fibrosis (cardiac cirrhosis); gut congestion with symptoms of early satiety, dyspepsia, or indigestion; and fluid retention with leg swelling (BMJ Best Practice 2024).

The patient will generally be referred by a general practitioner 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 (Arsalan, Walther et al. 2015, Meyer, Hays et al. 2021, Lancellotti, Pibarot et al. 2022). Transthoracic echocardiography 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 visualization of all leaflets simultaneously (Arsalan, Walther et al. 2015, Meyer, Hays et al. 2021, Lancellotti, Pibarot et al. 2022). Additionally, the mechanism of TR, degree of annual dilatation, and the presence of tethering should also be evaluated by echocardiography (BMJ Best Practice 2024). For significant TR, TEE is recommended and allows a complementary image, including both mid-oesophogeal and trans-gastric views. The ASE have published guidelines that provide an overview of various TR imaging technologies. In Australia, TR is graded as per the current ASE guidelines (Otto, Nishimura et al. 2021). The severity is graded based on parameters such as vena contracta (VC) width, effective regurgitant orifice area (EROA), regurgitant volume, and continuous-wave Doppler spectral appearance. The ASE also recommend

a multiparametric approach that combines spectral Doppler, colour Doppler, and 3D imaging data to ensure diagnostic accuracy. The grading system includes a classification ranging from mild to torrential TR, based on VC and EROA measurements. The presence of flow reversal in the hepatic vein is an important indicator of significant TR. In cases of poor echocardiographic quality or discordant findings, additional imaging modalities like cardiac magnetic resonance imaging (MRI) or computed tomography (CT) can be used for further clarification.

Table 1: Grading the Severity of chronic TR by echocardiography

Parameters	Mild	Moderate	Severe
Structural			
TV morphology	**Normal or mildly abnormal leaflets**	Moderately abnormal leaflets	**Severe valve lesions**
RV and RA size	Usually normal	Normal or mild dilatation	Usually dilated
Inferior vena cava diameter	Normal < 2 cm	Normal or mildly dilated 2.1-2.5 cm	Dilated > 2.5 cm*
Qualitative Doppler			
Colour flow jet area†	**Small, narrow, central**	Moderate central	**Large central jet** or eccentric wall-impinging jet of variable size
Colour flow convergence zone	**Not visible, transient or small**	Intermediate in size and duration	**Large throughout systole**
CWD jet	Faint/partial/parabolic	Dense, parabolic or triangular	Dense, often triangular
Semiquantitative			
Colour flow jet area (cm^2) †	Not defined	Not defined	>10
VCW (cm) †	<0.3	0.3-0.69	≥0.7
PISA radius (cm) ‡	≤0.5	0.6-0.9	>0.9
Hepatic vein flow§	Systolic dominance	Systolic blunting	**Systolic flow reversal**
Tricuspid inflow§	**A-wave dominant**	Variable	E-wave >1.0 m/sec
Quantitative			
EROA (cm^2)	<0.20	0.20-0.39	**≥0.40**
RVol (2D PISA) (mL)	<30	30-44	≥45

RA, Right atrium.
Bolded signs are considered specific for their TR grade.
RV and RA size can be within the "normal" range in patients with acute severe TR.
†With Nyquist limit >50-70 cm/sec.
‡With baseline Nyquist limit shift of 28 cm/sec.
§Signs are nonspecific and are influenced by many other factors (RV diastolic function, atrial fibrillation, RA pressure).
Source: (Davidson, Tang et al. 2024)

In line with the FDA approval in February 2024, the EVOQUE 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. The planned indication for the EVOQUE system in Australia is expected to mirror the FDA's approved use, ensuring alignment with clinical evidence. TGA Priority Applicant Determination application for EVOQUE has been approved, with a proposed indication of EVOQUE being 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. 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.

Provide a rationale for the specifics of the eligible population:

The proposed population is consistent with the population from the pivotal TRISCEND and TRISCEND II trials. The inclusion criteria specify signs and symptoms of TR, with grading of at least severe TR despite OMT. The proposed MBS item does not specify exclusion criteria, but it is expected that these would be realised in practice through the multidisciplinary Heart Team who determine eligibility for the procedure.

Inclusion Criteria:

- Signs/SYMPTOMS of TR or prior heart failure hospitalisation
- TR ≥ severe despite OMT

Exclusion Criteria:

- Anatomy precluding proper implant
- LVEF (left ventricular ejection fraction) < 25%
- Evidence of severe RV dysfunction
- Severe renal insufficiency (Estimated glomerular filtration rate ≤25 mL/min/1.73m^2 or requiring chronic renal replacement therapy)
- Severe pulmonary hypertension (Pulmonary artery systolic pressure >60 mmHg by echo Doppler or >70 mmHg by right heart catheterisation (RCH), or pulmonary vascular resistance >5 Wood units by RHC)

Are there any prerequisite tests?

Yes

Are the prerequisite tests MBS funded?

Yes

Provide details to fund the prerequisite tests:

Prior to use, the patient’s eligibility primarily depends on the anatomic conditions based on CT scan and echocardiographic imaging

MBS item 56807 – CT scan of the chest, abdomen, and pelvis with intravenous contrast medium,

MBS item 55126 - Initial real time transthoracic echocardiographic examination of the heart with real time colour flow mapping from at least 3 acoustic windows

MBS item 22051 - Transoesophageal echocardiography - Monitoring in real time of the structure and function of the heart chambers, valves and surrounding structures, including assessment of blood flow.

Intervention

Name of the proposed health technology:

Transcatheter tricuspid valve replacement

Describe the key components and clinical steps involved in delivering the proposed health technology:

After general anaesthesia is induced, the patient is intubated. A TEE probe is inserted and positioned. Femoral vein access is obtained, after which, under fluoroscopic guidance, a guidewire is inserted and advanced across the tricuspid valve. After the access site is dilated to accommodate the 28 French delivery system, the delivery system (with valve) is advanced over the guidewire into the right atrium of the heart. A combination of fluoroscopic and echocardiographic guidance is used to advance the valve delivery catheter via the vena cava to the right atrium. The position is confirmed, and the system is advanced into the right atrium and into the right ventricle (RV) for deployment of the valve within the tricuspid plane as determined by fluoroscopy and TEE. 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 withdrawn across the valve and from the right atrium. The catheter is retracted and removed from the access site; venous access is closed. Proper positioning and functioning of the valve, including the assessment of any paravalvular leakage, is confirmed by TEE. Measurement of regurgitation and the resultant gradients is assessed.

Key Components of the EVOQUE System:

- The EVOQUE system is the world's first transcatheter tricuspid valve replacement system (TTVR) designed to reduce tricuspid regurgitation.
- The EVOQUE valve's intra-annual sealing skirt and frame are designed for anatomic compatibility meaning ore patients may benefit from TR valve replacement.
- The EVOQUE valve uses ThermaFix tissue technology with proven durability and has nine ventricular anchors to engage native leaflets for secure placement.
- The low-profile EVOQUE delivery system with three planes of movement is designed for controlled delivery in a wide range of tricuspid anatomies which enables EVOQUE valve deployment in an atraumatic manner.
- Four different valve sizes (44, 48, 52, and 56mm) were developed to treat a wide range of tricuspid anatomies including patients with enlarged hearts due to TR.

Identify how the proposed technology achieves the intended patient outcomes:

TTVR achieves intended patient outcomes by providing a minimally invasive solution specifically designed for severe symptomatic TR despite OMT. Its transcatheter design enables implantation via a catheter, avoiding the need for open-heart surgery—a significant benefit for elderly or frail patients with comorbidities. 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 ≤ moderate TR and 95.3% achieving ≤ mild TR at 1-year follow-up (core lab adjudicated). This as a result led to significant KCCQ improvements, with a mean between-group difference in KCCQ-OS of 17.8 points at 1 year, substantially exceeding the validated minimal clinically important difference of 5 points.

Does the proposed health technology include a registered trademark component with characteristics that distinguishes it from other similar health components?

Yes

Explain whether it is essential to have this trademark component or whether there would be other components that would be suitable:

The proposed MBS item for TTVR specifies the procedure be conducted using the EVOQUE device. A preliminary review of the literature identified a number of medical devices for use in TTVR (Seligman, Vora et al. 2023), however none are currently listed on the ARTG. In addition, EVOQUE is the only device with randomised controlled trial evidence available, and it is unclear whether alternative devices would result in equivalent efficacy and safety outcomes, given the lack of comparative data between devices. The evidence to be presented in the ADAR would relate to the EVOQUE system only.

The Applicant is committed to working with the Department of Health and Medical Services Advisory Committee to ensure that the MBS item accurately reflects the clinical evidence available for TTVR, noting the potential differences between devices.

Notably, the proposed MBS item specifies tricuspid valve replacement and would not include transcatheter tricuspid valve repair. Previous studies evaluating tricuspid valve 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, Makkar et al. 2024). As such, TTVR and transcatheter tricuspid valve repair should not be considered interchangeable.

Are there any proposed limitations on the provision of the proposed health technology delivered to the patient (For example: accessibility, dosage, quantity, duration or frequency):

Yes

Provide details and explain:

The TTVR procedure can only be performed at specialised cardiac centres by certified heart specialists who have expertise in structural heart procedures. To be eligible for treatment, patients must meet several criteria, in line with the MBS proposed descriptor. This procedure is intended to be performed only once per lifetime. To ensure the best possible outcomes, a multidisciplinary

heart team is required to carefully evaluate each potential patient to determine if they are suitable candidates for the treatment.

If applicable, advise which health professionals will be needed to provide the proposed health technology:

The TTVR procedure could be conducted by appropriately trained interventional cardiologists or cardiothoracic surgeons.

If applicable, advise whether delivery of the proposed health technology can be delegated to another health professional:

No

If applicable, advise if there are any limitations on which health professionals might provide a referral for the proposed health technology:

Referral to TTVR would be determined by the patient's specialist, likely a cardiologist. Eligibility for TTVR would be determined by a multidisciplinary heart team including at least an interventional cardiologist or cardiothoracic surgeon, an imaging cardiologist who is trained on TEE imaging, and an anaesthesiologist. The implantation can be performed by either an interventional cardiologist or the cardiac surgeon.

Is there specific training or qualifications required to provide or deliver the proposed service, and/or any accreditation requirements to support delivery of the health technology?

Yes

Provide details and explain:

The implanting physicians should have advanced technical knowledge and experience in related catheter-based procedures. In addition, a comprehensive training program is provided by Edwards Lifesciences and must be completed before use of the EVOQUE system. The specific training and qualification requirements involve several steps for the implant team, specifically targeting Implanting Physicians and Echocardiographers:

Initial Training Requirements: Before performing the first procedure, the Implant Team must complete the following:

- A didactic session covering device and procedural information.
- Hands-on product training that includes device procedural steps and deployment practice using both a benchtop model and a physiologic model, with a minimum of two device deployments on the latter.

Supplemental Training: This is necessary if:

- More than 90 days pass between procedures for an Implanting Physician or Echocardiographer.
- There are updates to the device or procedure, which would require training on any new changes through a didactic session and hands-on product training

Accreditation and Documentation:

- Training is conducted by an Edwards Trainer, who is a certified specialist or subject matter expert responsible for ensuring the team is trained and that training is documented.
- All training sessions must be documented using the TMTT (transcatheter mitral and tricuspid therapies) Physician Training Form, which records completion of the didactic and hands-on sessions, trainer details, and trainee signatures.

Indicate the proposed setting(s) in which the proposed health technology will be delivered:

(Select all relevant settings)

☐ Consulting rooms
☐ Day surgery centre
☐ Emergency Department
☒ Inpatient private hospital
☒ Inpatient public hospital
☐ Laboratory
☐ Outpatient clinic
☐ Patient's home
☐ Point of care testing
☐ Residential aged care facility
☐ Other (please specify)

Is the proposed health technology intended to be entirely rendered inside Australia?

Yes

Provide additional details on the proposed health technology to be rendered outside of Australia:

N/A

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 healthcare system). This includes identifying healthcare resources that are needed to be delivered at the same time as the comparator service:

In the TRISCEND II pivotal trial, patients without the EVOQUE device, were on stable oral diuretic medications, most commonly Frusemide 40mg. Patients with severe TR usually present with signs or symptoms of right sided heart failure (HF), including peripheral oedema and ascites. As a result, current guidelines (ACC/AHA) recommend diuretics as the cornerstone for medical management in TR, specifically to relieve symptoms of right sided HF(Otto, Nishimura et al. 2021). No particular loop diuretic has demonstrated significant advantages versus the other (Ambrosino,

Sangoi et al. 2024). It is important to note that diuretics in TR have no morbidity or mortality benefit.

List any existing MBS item numbers that are relevant for the nominated comparators:

None

Provide a rationale for why this is a comparator:

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 replacement and other chronic conditions such as AF, kidney dysfunction and ischaemic coronary disease (Wang and Lal 2023). Research has revealed mortality after TR surgery is high, with early mortality rates ranging from 10% to 30% (Fender, Zack et al. 2018). In addition, surgical treatment of isolated TR is challenging due to factors such as right ventricular dysfunction and hepatorenal dysfunction due to chronic venous hypertension, often in patients who have previously undergone cardiac surgery (Sorajja P 2023). As such, the standard of care for these patients is optimised medical management, which typically consists of loop diuretics. This is in alignment with international guidelines (Wang and Lal 2023) and the TRISCEND II RCT.

Pattern of substitution – Will the proposed health technology wholly replace the proposed comparator, partially replace the proposed comparator, displace the proposed comparator or be used in combination with the proposed comparator?

☐ None (used with the comparator)
☐ Displaced (comparator will likely be used following the proposed technology in some patients)
☒ Partial (in some cases, the proposed technology will replace the use of the comparator, but not all)
☐ Full (subjects who receive the proposed intervention will not receive the comparator)

Outline and explain the extent to which the current comparator is expected to be substituted:

As per the TRISCEND II RCT, TTVR is intended to be provided alongside OMT.
Based on a retrospective analysis of patients treated with the EVOQUE device under compassionate use between 2019 and 2021 at multiple centres in Europe, the United States, and Canada, the dosage of loop diuretics for patients on the comparator was reduced following the use if the EVOQUE device for TTVR (Stolz, Weckbach et al. 2023). The mean dosage of loop diuretics was decreased from an average of 85 mg/day at baseline to 56 mg/day at discharge, and it remained at approximately 60 mg/day during follow-up.

Outcomes

List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be measured in assessing the clinical claim for the proposed medical service/technology (versus the comparator):

(Please select your response)

☒ Health benefits
☒ Health harms
☒ Resources
☐ Value of knowing

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

The primary analysis of this outcome from TRISCEND II demonstrated that EVOQUE is superior to OMT based on an improvement in both clinical events and quality of life (Hahn, Makkar et al. 2024).

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. Cardiovascular mortality, and other major cardiovascular adverse events will be presented.

Reduction in tricuspid regurgitation severity 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.

Major Health Benefits

TR Grade Reduction:
The TRISCEND II trial demonstrates unprecedented TR grade reduction, with 99.1% of TTVR recipients achieving ≤ moderate TR and 95.3% achieving ≤ mild TR at 1-year follow-up (core lab adjudicated). This dramatic improvement in valvular function represents a paradigm shift in TR management, as current medical therapy showed only 16.1% achieving ≤ moderate TR in the control arm at 1-year. The sustainability of TR reduction with the EVOQUE system through 1 year is particularly noteworthy given historical challenges with TR interventions. The magnitude of effect significantly exceeded that seen in prior tricuspid interventional studies, though cross-trial comparisons should be made cautiously.

Disease-Specific Quality of Life Improvement:
The trial demonstrated a mean between-group difference in KCCQ-OS of 17.8 points (95% CI 13.0-22.5) at 1 year, substantially exceeding the validated minimal clinically important difference of 5 points. This improvement manifested early (11.8-point difference at 30 days) and was sustained through follow-up. Domain analysis revealed comprehensive benefits across physical limitations (+10.7), total symptoms (+16.8), quality of life (+23.4) and social limitations (+21.5). The effect size exceeded that typically seen in heart failure device trials.

Functional Status Improvement:
NYHA class improvement of ≥1 class showed an absolute difference of 54.9% between groups at 1 year (78.9% TTVR vs 24.0% control, $p<0.001$). The 6-minute walk distance improvements, while

modest in absolute terms, demonstrated durability through 1 year. Importantly, subgroup analyses suggest patients with better baseline functional capacity (6MWD ≥238.5m) derived greater benefit (interaction p=0.016), which has implications for both patient selection and health economic modelling.

Minor Health Benefits

Heart Failure Hospitalisation Reduction:
The trial demonstrated a 5.2% absolute reduction in heart failure hospitalisation at 1 year (20.9% vs 26.1%). While this did not reach statistical significance, the direction and magnitude of effect is clinically relevant given the high-cost burden of heart failure hospitalisations. The Kaplan-Meier curves suggest early separation, maintained through follow-up. The win ratio analysis incorporating HF hospitalisation (Win Ratio 2.02, 95% CI 1.56-2.62) supports the clinical significance of this finding.

All-Cause Mortality Trend:
The trial showed a numerical reduction in CEC-adjusted 1-year all-cause mortality (12.6% vs 15.2%). The early hazard of procedural mortality (3.1% at 30 days) appears to be offset by better late outcomes, with landmark analysis from 30 days showing continued divergence of survival curves. This pattern is consistent with other transcatheter valve therapies where procedural risk is balanced against long-term benefit.

Major Health Harms

Procedural and Late Safety Events:
The safety profile of the procedure highlights significant early and late risks that must be factored into clinical decision-making, especially given the elderly, often anticoagulated patient population. In the 30-day period, a severe bleeding rate of 10.4% (vs. 1.5% in control), a new pacemaker implantation rate of 24.7% in pacemaker-naïve patients, and a 1.2% conversion to surgery rate underscore the need for careful patient selection. Additionally, in the 31–365-day period, notable event rates continue with 5.7% cardiovascular mortality. However, there was a reduction in severe bleeding (5.3%), and 4.2% new pacemaker implantation in previously pacemaker-naïve patients.

Resources:

Procedure & follow up care resources:
- Interventional Cardiologist
- Cardiac Surgeon (for Heart Team assessment - mentioned in trial governance)
- Cardiac Imaging Specialist (Trial used dedicated echo core lab)
- Clinical Nurse Coordinator
- Rehab team

Screening Requirements:
- Echocardiography department/staff
- Cardiac catheterisation lab staff for assessment
- Pathology laboratory

Procedure resources:
- Cardiac Catheterisation Laboratory
- Equipment for transfemoral access

- Imaging systems

Recovery:

- CCU/ICU beds (given 3-day median stay)
- Critical Care Nurses
- Ward Nurses

Proposed MBS items

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

TTVR is currently not funded in Australia.

Within the national coverage determination (NCD) process in the United States, the Centers for Medicare and Medicaid Services (CMS) has issued Coverage with Evidence Development (CED) for EVOQUE. This is in recognition of the need to balance the urgent need to provide a suitable treatment option for patients suffering with TR with the earliness of the TRISCEND II data. Under the NCD with CED, Edwards is required to commit to continued evidence development for EVOQUE and increased representation of the sub-populations of interest for Medicare coverage.

Provide at least one proposed item with their descriptor and associated costs, for each Population/Intervention:

MBS item number (where used as a template for the proposed item)	XXXX
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	$1,631.65 - $1800
Indicate the overall cost per patient of providing the proposed health technology	$1,631.65 - $1800
Please specify any anticipated out of pocket expenses	N/A
Provide any further details and explain	N/A

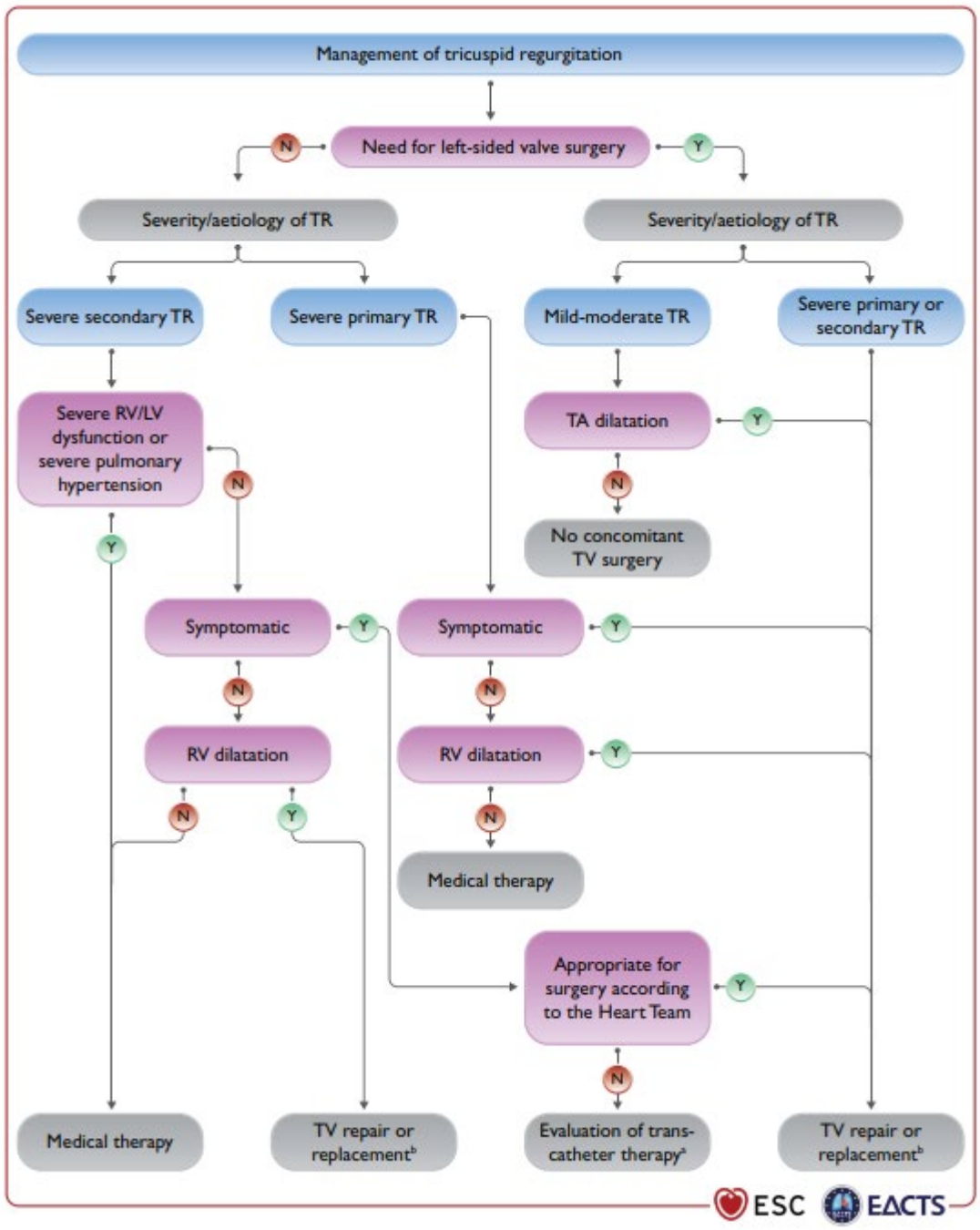
The proposed MBS fee is based on the existing fee for transcatheter mitral valve repair, as it is expected that the procedures will require a similar level of time, skill and training to provide.

Algorithms

PREPARATION FOR USING THE HEALTH TECHNOLOGY

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, before patients would be eligible for the proposed health technology:

Figure 1: Proposed Clinical Management Algorithm for EVOQUE



Source: (Vahanian, Beyersdorf et al. 2021)

The proposed clinical management algorithm for TTVR is shown in Figure 1. Similarly to other structure heart indications, patients will receive testing to determine the need for valve surgery, TR severity and TR aetiology. The procedure is typically considered for symptomatic patients with

severe TR despite OMT. More specifically there are several prerequisite tests and healthcare resources needed to determine eligibility for TTVR. The key tests and resources include:

Initial Clinical Evaluation:

- Assessment by a General Practitioner to review medical history for conditions associated with TR, including heart failure and other comorbidities.

Diagnostic Imaging:

- TTE: Used as the primary imaging modality to evaluate the valve structure and TR severity.
- TEE: Provides detailed images, particularly when TTE results are inconclusive.
- CT Scan: Required for assessing 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. This team assesses the patient's overall risk, anatomy, and eligibility for the transcatheter procedure.

Is there any expectation that the clinical management algorithm before the health technology is used will change due to the introduction of the proposed health technology?

No

Describe and explain any differences in the clinical management algorithm prior to the use of the proposed health technology vs. the comparator health technology:

N/A, clinical management algorithm and resource utilisation will be the same.

USE OF THE HEALTH TECHNOLOGY

Explain what other healthcare resources are used in conjunction with delivering the proposed health technology:

Proposed resources to identify eligible population: TTE, TEE, anaesthesiology for TEE, electrocardiography, chest x-ray, CT scan, cardiac catheterisation, cardiology consultation, surgical consultation, anaesthetic consultation, heart team consultation. Resources to deliver proposed intervention: Edwards EVOQUE delivery system, alongside Edwards EVOQUE dilator kit and loading system, surgical assistant, anaesthesiology, catheterisation/hybrid lab, theatres, intensive care unit, coronary care unit, TTE, cardiology consultation, pharmaceuticals. For the delivery of the EVOQUE system, Edwards can provide optional accessories that includes the stabiliser, base and plate that are intended to secure the delivery system at an angle appropriate for the transfemoral venous approach and to enable fine adjustments of the position of the delivery system during the implantation procedure.

Table 3 presents the associated medial services that are needed to perform the TTVR procedure., this includes any clinic or hospital related costs.

Table 3: Medical Services included in the TTVR Procedure

Resources	Reference
Pre-procedural heart team assessment	MBS items: 6082 ($55.75) and 6084 ($41.50)
EVOQUE implantation fee	MBS item: XXXX ($1,631.65)
Anaesthesia	MBS item: 21936
Intra-operative transoesophageal echocardiography	MBS item: 55135, 55126, 55129, 55127,55134
CT scan	MBS item 56807
Hospital associated costs	DRG code F21: Other circulatory system GIs [1]
Post-procedural/pre-discharge transoesophageal echocardiography	MBS Item 55126, 55129, 55127, 55134

Note: 1. DRG F25 (Percutaneous Heart Valve Replacement with Bioprosthesis) may be applicable to the TTVR procedure. Current costs for this DRG will include the cost of alternative prostheses (e.g. SAPIEN valve) which cannot be removed from the DRG cost. As such, an alternative DRG is used for the base case.

Explain what other healthcare resources are used in conjunction with the comparator health technology:

The healthcare resources used to deliver the comparator technology include ongoing consultations with cardiologists and other specialists to deliver optimal medical management, as well as the pharmaceutical components of management.

Describe and explain any differences in the healthcare resources used in conjunction with the proposed health technology vs. the comparator health technology:

The appropriate comparator for the proposed medical service is OMT (typically diuretics), as currently the proposed patient populations are managed with medical therapy, due to their ineligibility for surgery. As such, the proposed medical service involves a new approach towards management in the proposed populations. The main difference between the proposed intervention and the comparator, is that the objective of the proposed medical service is to replace the tricuspid valve, whereas the proposed comparator provides symptom relief and prevention of disease progression only. TTVR provides a treatment option for who have symptomatic severe TR.

CLINICAL MANAGEMENT AFTER THE USE OF HEALTH TECHNOLOGY

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, after the use of the proposed health technology:

Continuous ECG Monitoring: This may be required to monitor for any conduction disturbances before the patient is discharged from the hospital.

Antibiotic Prophylaxis: Recommended for patients at risk of prosthetic valve infection and endocarditis to prevent infections following the procedure.

Anticoagulant/Antiplatelet Therapy: Patients should be maintained on this therapy as per current guidelines to minimise the risk of valve thrombosis or thromboembolic events.

Regular Follow-Up: Long-term durability of the EVOQUE valve has not been fully established, so regular follow-up is advised to evaluate valve performance. This includes assessments at discharge, 30 days, 3 months, 6 months, 1 year, and annually up to 5 years post-procedure.

Imaging Tests: These are part of the follow-up assessments and may include echocardiograms to monitor the valve and cardiac function.

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, after the use of the comparator health technology:

For OMT, typically it would require ongoing monitoring of weight, blood pressure, symptom exacerbation, alongside full blood tests for renal function and electrolytes.

Describe and explain any differences in the healthcare resources used after the proposed health technology vs. the comparator health technology:

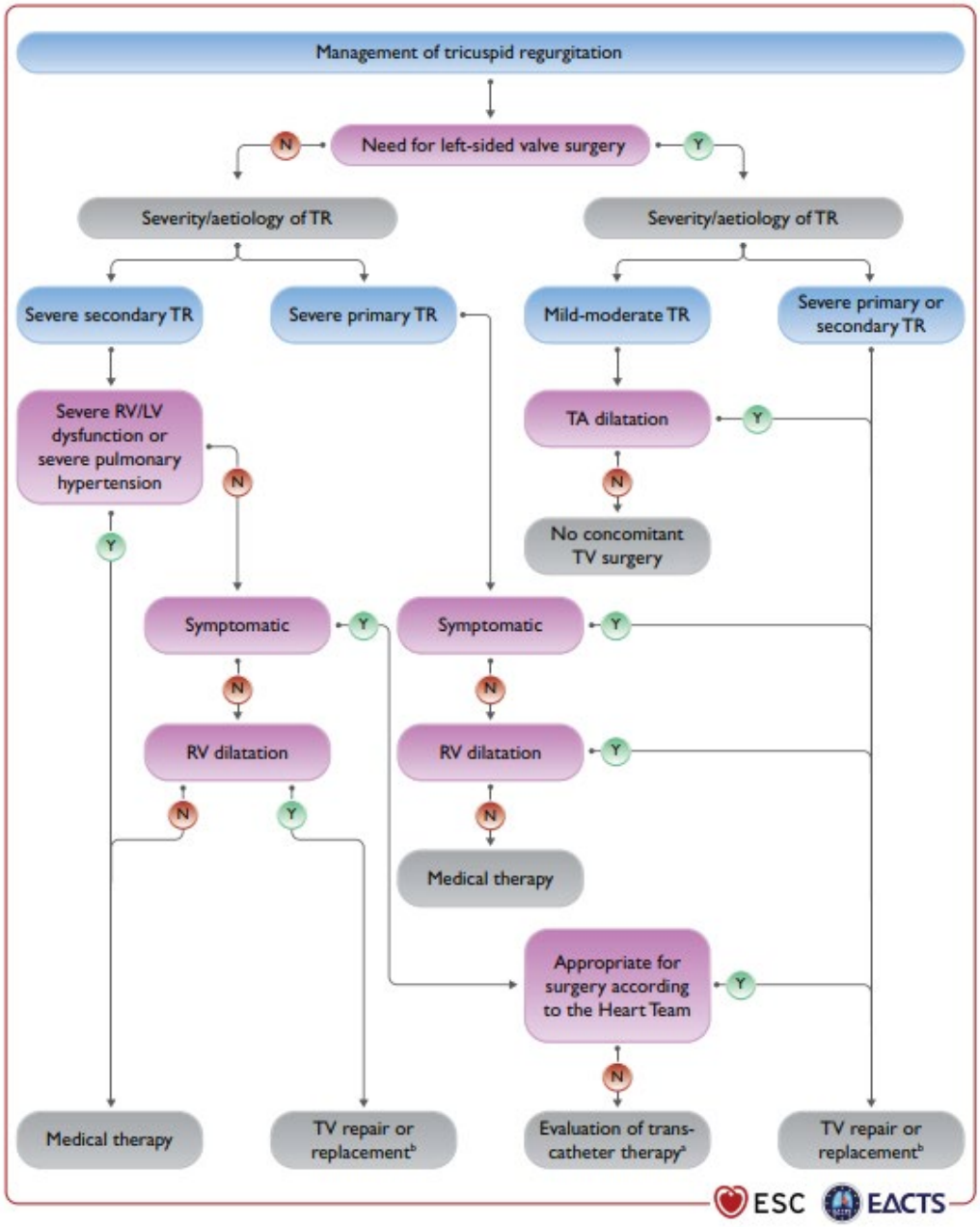
Monitoring and Follow-Up: TTVR demands structured, frequent follow-ups with regular imaging to assess valve function, whereas OMT requires periodic follow-ups focused on fluid status and symptom management.

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.

Insert diagrams demonstrating the clinical management algorithm with and without the proposed health technology:



Source: (Vahanian, Beyersdorf et al. 2021)

With the proposed health technology, patients with severe symptomatic TR are assessed for eligibility of transcatheter therapy by the MDHT. In those who are suitable, TTVR is performed.

Without the proposed health technology, these patients remain on OMT despite being poorly managed and continue to experience poor outcomes.

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)?

Efficacy of EVOQUE vs. Optimal Medical Therapy (OMT):
☒ Superior
☐ Non-inferior

☐ Inferior

Safety of EVOQUE vs. Optimal Medical Therapy (OMT):
☐ Superior
☒ Non-inferior
☐ Inferior

Please state what the overall claim is, and provide a rationale:

Claim Summary: The EVOQUE device demonstrates superior efficacy over optimal medical therapy (OMT) in reducing TR and improving health outcomes, as indicated by the TRISCEND II trial results. In terms of safety, EVOQUE is considered non-inferior to OMT for long-term adverse events, with manageable procedural risks.

The clinical claim to be presented in this application is based on analysis of individual measures contributing to the composite outcome in the TRISCEND II RCT (Hahn et al., 2024). 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
- Annualized rate of hospitalization 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, this application will also present individual components of the composite measure.

Rationale: The pivotal TRISCEND II trial, involving 400 patients with symptomatic severe TR, showed a significant clinical benefit of TTVR with the EVOQUE system over OMT. The primary composite outcome demonstrated a win ratio of 2.02 (95% CI, 1.56 to 2.62; P<0.001), favouring TTVR with EVOQUE. Clinical benefit was evaluated by the hierarchical composite safety and effectiveness endpoints at 1-year.

Primary Outcome Components for EVOQUE vs control at 1 year:

- All-cause Mortality: 11.6% in valve replacement group vs 10.5% in control group
- RVAD (right ventricular assist device) or heart transplant: There was no RVAD or heart transplant in either group.
- Tricuspid intervention: 0.8% in valve replacement group vs 3.0% in control group
- Heart Failure Hospitalisation (HFH): 20.9% in the valve replacement group vs 26.1% in the control group based on Kaplan Meier data
- Quality of Life (KCCQ-OS): Improvement in KCCQ-OS scores by at least 10 points was achieved in 66.4% in valve replacement group vs 36.5% in control group
- Functional Class (NYHA Class): Improvement of at least 1 NHYA class was achieved in 78.9% of valve replacement patients vs 24.0% of control patients
- 6-Minute Walk Distance (6MWD): Improvement in 6MWD of at least 30 meters was 47.6% in valve replacement group vs 31.8% in control group

In the TRISCEND II RCT, reduction in TR grade was a pre-specified secondary effectiveness endpoint. TTVR significantly reduced TR severity, with 95.3% of patients achieving mild or less TR at 1 year, compared to only 2.3% of control patients.

Safety and Adverse Events: TTVR was associated with some adverse events. Late-stage safety outcomes (31 to 365 days) for the TTVR device were non-inferior to optimal medical therapy. The reasons are listed below:

Cardiovascular Mortality:

- Days 1–29: The early cardiovascular mortality rate in the TTVR group was higher than in the control, reflecting the initial risks associated with the procedure.
- Days 31–365: The cardiovascular mortality rate for TTVR decreased over time, resulting in a slightly lower rate (5.7%) compared to the control (7.8%) during the late stage. This suggests that while the immediate post-procedure period carries higher mortality risk, TTVR achieves non-inferiority over the longer term.
- Cumulatively, there was no significant difference in cardiovascular mortality between the valve repair and control arms (8.5% vs 7.5% respectively; p = 0.85).

Myocardial Infarction and Stroke:

- Days 1–29: Rates of myocardial infarction and stroke were low in both groups, though the TTVR group showed a slightly higher incidence.
- Days 31–365: Late-stage myocardial infarction (1.2% in TTVR vs. 0.8% in control) and stroke rates (1.2% in TTVR vs. 0.0% in control) remained low. The slight increase in these events in TTVR suggests only a marginal difference without a significant risk increase over time.
- Cumulatively, there was no significant difference in the rate of either myocardial infarction or stroke between the treatment arms.

Severe Bleeding:

- Days 1–29: Early severe bleeding rates were higher in the TTVR group compared to control, likely related to procedural risks.
- Days 31–365: Severe bleeding rates in the late stage were comparable between TTVR (5.3%) and control (4.7%). The reduced late-stage bleeding rate in TTVR suggests that bleeding risks stabilize after the initial period, supporting its non-inferiority in bleeding risk over time.

Nonelective Tricuspid Valve Reintervention:

- Days 1–29: Reinterventions were minimal in both groups in the early phase.
- Days 31–365: TTVR showed no need for reinterventions (0%), while the control group required a 2.3% reintervention rate. This difference highlights a potential advantage of TTVR in reducing future valve interventions after the initial post-procedural period.

New Pacemaker/CIED (cardiac implantable electronic device) Implantation:

- Days 1–29: Early implantation rates of pacemakers or other cardiac devices were slightly higher in TTVR due to procedural necessity.

- Days 31–365: The need for new pacemaker/CIED implantation remained similar between TTVR (4.2%) and control (3.9%) over the longer term, indicating that TTVR does not increase dependency on these devices after the initial procedure.

The safety profile for TTVR in the early days 1–29 shows higher adverse event rates, as expected with initial procedural risks. However, from days 31–365, the rates stabilise, demonstrating non-inferiority and, in some cases, advantages like reduced reinterventions. TTVR provided superior clinical benefits and met the composite primary safety and effectiveness endpoint at 1 year, with 62.1% of TTVR patients showing a clinical benefit, compared to 30.7% in the OMT group. Patients experience a 2 x greater likelihood of clinical benefit with TTVR vs OMT alone.

Why would the requestor seek to use the proposed investigative technology rather than the comparator(s)?

The ideal candidate for the TTVR procedure is someone living with severe TR, whose quality of life has been significantly impacted despite OMT. These are patients for whom everyday activities have become challenging due to breathlessness, fatigue, or swelling. Medical therapy alone has not provided sufficient relief, leaving them struggling with the burdensome symptoms of TR.

For these patients, the limitations imposed by TR are often profound. Their declining health may also mean they face a high surgical risk, making traditional open-heart surgery an unsafe or unacceptable option. TTVR, offers these individuals a valuable alternative. The device provides a less invasive approach, aimed not at simply prolonging life but at restoring a better quality of life.

Recently, the FDA utilised patient preference data from a survey administered at baseline to all patients in the TRISCEND II study as a basis to inform recent approval of the EVOQUE system in the United States. The TRISCEND II patient preference survey aimed to understand patient priorities for relief from TR symptoms and patient disease burden and experience. Included in the results highlighted by the FDA, 53% of patients ranked "caring for yourself"' as the most important activity for improvement and 41% rated "shortness of breath" as the most important symptom to see improvement.

Separately, Iyer, Faza et al. (2024) investigated patient treatment preferences where an online survey was administered and completed by 150 patients with TR. The survey showed that patients with TR are willing to accept higher procedural intervention risk if shortness of breath is alleviated, and this risk tolerance is higher for older and more symptomatic patients. Differences were also observed between patients with less severe versus more severe disease; those with New York Heart Association (NYHA) Class I/II disease more strongly preferred avoiding procedural reintervention risk compared with those with Class III/IV TR.

Identify how the proposed technology achieves the intended patient outcomes:

TTVR achieves intended patient outcomes by providing a minimally invasive solution specifically designed for severe symptomatic TR despite OMT. Its transcatheter design enables implantation via a catheter, avoiding the need for open-heart surgery—a significant benefit for elderly or frail patients with comorbidities. 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.

For some people, compared with the comparator(s), does the test information result in:

A change in clinical management?

A change in health outcome? Yes

Other benefits? Yes

Please provide a rationale, and information on other benefits if relevant:

Benefits described above.

In terms of the immediate costs of the proposed technology (and immediate cost consequences, such as procedural costs, testing costs etc.), is the proposed technology claimed to be more costly, the same cost or less costly than the comparator?

(Please select your response)

☒ More costly
☐ Same cost
☐ Less costly

Provide a brief rationale for the claim:

EVOQUE is expected to be more costly than optimal medical therapy (OMT) because OMT does not require any surgical intervention. Unlike EVOQUE, OMT is associated with no costs related to a procedure, such as operating room time, specialised equipment, or skilled surgical staff. Additionally, OMT incurs no costs from procedure-related complications, hospital stays, or recovery periods, making it inherently less expensive.

Summary of Evidence

Provide one or more recent (published) high quality clinical studies that support use of the proposed health service/technology.

	Type of study design*	**Title of journal article or research project** ***(including any trial identifier or study lead if relevant)***	**Short description of research** ***(max 50 words)****	**Website link to journal article or research** ***(if available)***	**Date of publication*****
1	The TRISCEND II trial (pivotal study) is a prospective, multicenter, randomised, open-label trial.	Quality of Life After Transcatheter Tricuspid Valve Replacement: 1-Year Results from the TRISCEND II Pivotal Trial	This study investigates the health outcomes of the EVOQUE tricuspid valve replacement system (TTVR) combined with optimal medical therapy (OMT) compared to OMT alone in patients with symptomatic and severe or greater TR. The trial evaluates improvements in quality of life, symptoms, and functional status over one year.	(Arnold Suzanne et al., 2024) https://www.jacc.org/doi/10.1016/j.jacc.2024.10.067	30th October 2024
2	The TRISCEND II trial is a prospective, multicenter, randomised, open-label trial.	Transcatheter Valve Replacement in Severe TR	Data regarding outcomes after percutaneous transcatheter tricuspid-valve replacement are needed.	(Hahn et al., 2024) https://www.nejm.org/doi/abs/10.1056/NEJMoa2401918#:~:text=For%20patients%20with%20severe%20tricuspid,.gov%20number%2C%20NCT04482062.)	30th October 2024

	Type of study design*	**Title of journal article or research project** ***(including any trial identifier or study lead if relevant)***	**Short description of research** ***(max 50 words)****	**Website link to journal article or research** ***(if available)***	**Date of publication*****
3	Hahn RT, et al. EVOQUE Tricuspid Valve Replacement System State-of-the-Art Screening and Intraprocedural Guidance. J Am Coll Cardiol Intv. 2024;17:2093-2122.	EVOQUE Tricuspid Valve Replacement System: State-of-the-Art Screening and Intraprocedural Guidance	This research focuses on the recently approved EVOQUE transcatheter tricuspid valve replacement system, designed to treat severe symptomatic tricuspid regurgitation (TR). It provides a comprehensive overview of the device's characteristics, patient selection criteria, and anatomical considerations necessary for successful outcomes	https://www.sciencedirect.com/science/article/abs/pii/S1936879824010318?via%3Dihub	23rd September 2024
4	Grayburn P, et al. TRISCEND II: Novel Randomized Trial Design for Transcatheter Tricuspid Valve Replacement. Am J Cardiol. 2024;225:171–177.	TRISCEND II: Novel Randomized Trial Design for Transcatheter Tricuspid Valve Replacement	This research focuses on the early results and outcomes of the RCT, TRISEND II	https://www.ajconline.org/article/S0002-9149(24)00435-1/abstract	August 15th 2024
5	Kodali S, et al. Transfemoral Tricuspid Valve Replacement at One Year: The TRISCEND Study (single arm study). Euro Heart J. 2023;44:4862-4873.	Transfemoral tricuspid valve replacement and one-year outcomes: the TRISCEND study	This research focuses on the evaluation of the EVOQUE transcatheter tricuspid valve replacement (TTVR) system in patients with symptomatic, moderate to severe tricuspid regurgitation (TR) who are unsuitable for surgical intervention. The TRISCEND study, a global, multicenter, single-arm prospective trial, reports interim one-year outcomes, emphasising procedural success, safety, and effectiveness of the EVOQUE system.	https://academic.oup.com/eurheartj/article/44/46/4862/7335468?login=false	December 2023

	Type of study design*	**Title of journal article or research project** ***(including any trial identifier or study lead if relevant)***	**Short description of research** ***(max 50 words)****	**Website link to journal article or research** ***(if available)***	**Date of publication*****
6	Webb JG, et al. Transcatheter tricuspid valve replacement with the EVOQUE system: 1-year outcomes of a multicenter, first-in-human experience. JACC Cardiovasc Interv. 2022;15:481-491.	Transcatheter tricuspid valve replacement with the EVOQUE system: 1-year outcomes of a multicenter, first-in-human experience.	This study evaluated the 1-year outcomes of the EVOQUE transcatheter tricuspid valve replacement (TTVR) system in a compassionate-use cohort of 27 high-risk patients with severe tricuspid regurgitation (TR) and right-sided heart failure.	https://pubmed.ncbi.nlm.nih.gov/37930776/	March 2022
7	Kodali S, et al. Transfemoral tricuspid valve replacement in patients with tricuspid regurgitation: TRISCEND study 30-Day results. JACC Cardiovasc Interv. 2022;15:471-480.	Transfemoral tricuspid valve replacement in patients with tricuspid regurgitation: TRISCEND study 30-Day results.	This research evaluates the TRISCEND study to show the early clinical outcomes (30-days) of the transfemoral EVOQUE transcatheter tricuspid valve replacement (TTVR) system for treating severe tricuspid regurgitation (TR)	https://pubmed.ncbi.nlm.nih.gov/35272771/	March 2022
8	Fam NP, et al. Transfemoral transcatheter tricuspid valve replacement with the EVOQUE system: a multicenter, observational, first-in-human experience. JACC Cardiovasc Interv. 2021;14:501-511.	Transfemoral transcatheter tricuspid valve replacement with the EVOQUE system: a multicenter, observational first-in-human experience.	This first-in-human, observational study evaluated the EVOQUE transcatheter tricuspid valve replacement (TTVR) system in 25 high-risk patients with severe tricuspid regurgitation (TR) and heart failure. The study demonstrated the feasibility, safety, and short-term clinical impact of this novel system.	https://www.sciencedirect.com/science/article/pii/S1936879820323876?via%3Dihub	March 2021

	Type of study design*	**Title of journal article or research project** ***(including any trial identifier or study lead if relevant)***	**Short description of research** ***(max 50 words)****	**Website link to journal article or research** ***(if available)***	**Date of publication*****
9	Retrospective analysis	2-Year Outcomes Following Transcatheter Tricuspid Valve Replacement Using the EVOQUE System	This study examines the two-year survival, symptomatic, and echocardiographic outcomes, as well as adverse events, for patients undergoing transcatheter tricuspid valve replacement (TTVR) with the EVOQUE system in a compassionate use setting across centres in Europe, the U.S., and Canada. The findings indicate high procedural success, sustained TR reduction, and improvements in functional status, with minimal complications over a two-year follow-up period.	(Stolz et al., 2023) https://www.jacc.org/doi/10.1016/j.jacc.2023.04.014	June 2023

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes. For yet to be published research, provide high level information including population numbers and whether patients are being recruited or in post-recruitment.*

**** If the publication is a follow-up to an initial publication, please advise. For yet to be published research, include the date of when results will be made available (to the best of your knowledge)*

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