MSAC Application 1812

Transcatheter edge-to-edge repair (TEER) for the treatment of severe tricuspid regurgitation (TR) using the TriClip device

Applicant: Abbott Medical Australia Pty Limited

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 edge-to-edge repair for the treatment of severe tricuspid regurgitation

Component	Description
Population	Patients with severe tricuspid regurgitation (TR) who are symptomatic (New York Heart Association [NYHA] functional class II, III or ambulatory IV) despite treatment with optimal medical therapy (OMT), and who have systolic pulmonary artery pressure (sPAP) of ≤70 mmHg, and left ventricular ejection fraction (LVEF) of >20%, and are deemed by a qualified multidisciplinary heart team (MDHT) to be suitable for isolated transcatheter edge-to-edge repair (TEER)
Intervention	Transcatheter edge-to-edge repair of the tricuspid valve (T-TEER) in addition to continued OMT
Comparator	Continued OMT alone
Outcomes	**Safety outcomes:** • major cardiovascular (CV) events (myocardial infarction, stroke, CV death) • severe bleeding • major access site and vascular complications • major cardiac structural complications (e.g. coronary structure perforation) • conversion to surgery • new arrhythmia or conduction disorder requiring permanent pacing • new onset renal failure • endocarditis requiring surgery • tricuspid valve reintervention (percutaneous or surgical); explant • device-related events (e.g. detachment, embolisation, thrombosis) **Efficacy/effectiveness outcomes:** • mortality (all-cause, CV) • hospitalisation for heart failure • change in TR severity/grade • quality of life using disease-specific (e.g. Kansas City Cardiomyopathy Questionnaire [KCCQ]) and generic (e.g. 36-item Short Form Health Survey [SF-36]) tools • health status (New York Heart Association [NYHA] functional class and 6-minute walk test [6MWT]) • change in medical therapy (dose, frequency, type) **Healthcare resources (including patient out-of-pocket costs):** • cost of T-TEER prosthesis and other consumables • cost to deliver T-TEER 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)

Component	Description
	Cost-effectiveness: • cost per life year gained • cost per quality-adjusted life year (QALY) gained **Total Australian government healthcare costs** • total cost to the Medical Benefits Schedule (MBS) • total cost to the Pharmaceutical Benefits Scheme (PBS) **Total cost to private health insurers and hospitals** • total cost to the Prescribed List of Medical Devices and Human Tissue Products (PL) for T-TEER prosthesis and changes in use of other prostheses • total cost of hospitalisation for T-TEER, management of complications and reinterventions
Assessment question	What is the comparative safety, effectiveness and cost-effectiveness of T-TEER in addition to continued OMT versus OMT alone in patients with severe, symptomatic TR despite OMT and who are suitable for isolated T-TEER?

Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of transcatheter edge-to-edge repair (TEER) of the tricuspid valve (T-TEER)[1] for the treatment of severe, symptomatic tricuspid regurgitation (TR) despite optimal medical therapy (OMT) was received from Abbott Medical Australia Pty Limited by the Department of Health, Disability and Ageing.

PICO criteria

Population

The proposed population is patients with TR graded at least severe, as determined by echocardiography, with symptoms (New York Heart Association [NYHA] functional class II, III or ambulatory IV) that persist despite OMT, and who have systolic pulmonary artery pressure (sPAP) of ≤70 mmHg, and left ventricular ejection fraction (LVEF) of >20%.[2] To be eligible for the proposed intervention, patients must also be deemed by a qualified multidisciplinary heart team (MDHT) to be suitable for isolated T-TEER.

The proposed population aligns with that of the pivotal randomised controlled trial (RCT) evaluating the safety and efficacy of T-TEER using the TriClip Transcatheter Tricuspid Valve Repair System (hereafter referred to as the TriClip system) in addition to continued OMT, compared with OMT alone. This trial, referred to as TRILUMINATE Pivotal (NCT03904147; Sorajja et al. 2023), required participants to be at intermediate or greater estimated risk for mortality or morbidity associated with tricuspid valve surgery, as determined by the local heart team, and to be receiving stable OMT for at least 30 days. The applicability of the clinical evidence to the Australian target population needs to be addressed during the assessment.

[1] Suggested standardised terminology for tricuspid valve transcatheter edge-to-edge repair from the Tricuspid Valve Academic Research Consortium (TVARC) (Hahn et al. 2023).

[2] The application specified LVEF ≥20% and sPAP <70 mmHg as eligibility criteria. The assessment group amended these to LVEF >20% and sPAP ≤70 during PICO Confirmation development, such that the eligibility criteria would not be inconsistent with TRILUMINATE Pivotal exclusion criteria.

TRILUMINATE Pivotal participants were further selected based on the likelihood of achieving a meaningful reduction in TR following T-TEER. An independent eligibility committee that included a cardiac surgeon, an interventionalist, and an echocardiographer assessed this likelihood using criteria such as baseline TR severity, the number of tricuspid valve leaflet segments requiring treatment, and the size of anatomic leaflet gaps. Patients deemed likely to achieve moderate or less residual TR were enrolled in the RCT. Those expected to achieve at least a one-grade reduction in TR, but not moderate or less residual TR, were assigned to a concurrent single-arm cohort. Patients unlikely to experience any reduction in TR were excluded from the study (Sorajja et al. 2023; supplementary material).

Other key exclusion criteria in TRILUMINATE Pivotal were:

- tricuspid valve leaflet anatomy that may preclude clip implantation, proper clip positioning on the leaflets, or sufficient reduction in TR (e.g. evidence of calcification in the grasping area, presence of a severe coaptation defect of the tricuspid leaflets, severe leaflet defect preventing proper device placement, Ebstein anomaly)
- severe uncontrolled hypertension
- indication for left-sided (e.g. severe mitral regurgitation [MR]) or pulmonary valve correction in the prior 60 days.

Although the proposed population does not specify these additional criteria, the application noted that suitability will be confirmed via a multidisciplinary case conference to ensure appropriate patient selection.

PASC confirmed the proposed patient population. PASC noted that the pivotal clinical trial excluded patients with severely depressed ejection fraction and severe pulmonary hypertension. PASC considered that these patients have very high mortality and are unlikely to benefit from the intervention, making their exclusion appropriate. PASC also considered whether other trial exclusions – such as surgical ineligibility or the likelihood of achieving only moderate or less residual TR after the procedure – should be incorporated into the population definition. PASC recalled its previous discussion on whether to include surgical ineligibility in MSAC application 1799 for transcatheter tricuspid valve (TTV) replacement, where it was agreed that patients with severe, symptomatic TR are rarely suitable for, or offered, surgery. PASC noted that the applicant's clinical expert advised that some patients could derive clinical benefit from reducing TR severity from torrential or massive to severe. After discussion, PASC advised that the decision regarding suitability for T-TEER should remain at the discretion of the MDHT, and no changes to the population description were required.

Severe tricuspid regurgitation

TR is a valvular heart condition in which the tricuspid valve fails to close properly, resulting in the backflow of blood from the right ventricle into the right atrium. TR can arise from a range of aetiologies, broadly classified into primary and secondary causes. Primary TR is due to intrinsic abnormalities of the tricuspid valve leaflets. Common causes include infective endocarditis, rheumatic heart disease, blunt chest trauma, carcinoid syndrome, drug-induced damage, radiation exposure, and congenital anomalies such as Ebstein anomaly (Otto et al. 2021). Secondary (functional) TR accounts for approximately 90% of TR cases (Praz et al. 2025). It typically results from right ventricular (RV) remodelling due to pressure or volume overload, often associated with left-sided heart disease, chronic pulmonary hypertension, or dilated cardiomyopathy (Otto et al. 2021). Recent classifications further subdivide secondary TR into ventricular, atrial, and lead-associated forms, the latter referring to TR caused by cardiac implantable electronic devices (Hahn et al. 2023).

A distinct subtype, isolated TR, is increasingly recognised as a separate clinical entity (Otto et al. 2021; Prihadi et al. 2019). It typically occurs in elderly patients without pulmonary hypertension or left-sided

heart disease and is strongly associated with atrial fibrillation (AF). AF contributes to right atrial dilation, tricuspid annular enlargement, and malcoaptation of the valve leaflets (Prihadi et al. 2019). Prognosis in isolated TR is closely linked to the severity of regurgitation (Topilsky et al. 2014).

TR severity is traditionally graded as mild, moderate, or severe, based on guidelines from the American Society of Echocardiography (ASE) (Zoghbi et al. 2017). More recently, this grading system has been expanded to a five-grade scale, further stratifying the severe category into severe, massive, and torrential TR (Hahn et al. 2023). In clinical practice, the term 'severe TR' is often used as an umbrella term encompassing all three higher grades.

Data from the National Echocardiography Database of Australia (NEDA) indicate that among adults evaluated for heart disease, 21.4% had mild TR, 5.9% had moderate TR, and 1.8% had severe TR (Offen et al. 2022). Importantly, increasing TR severity is independently associated with higher risks of cardiovascular and all-cause mortality (Offen et al. 2022; Chorin et al. 2020). One-year mortality in patients with severe or worse TR exceeds 40%, with even higher rates over the long term. Additionally, higher TR grades are linked to increased heart failure hospitalisations and reduced quality of life (Chorin et al. 2020; Fujisawa et al. 2022).

Based on epidemiological modelling, the application estimated that approximately 29,260 individuals in Australia are living with severe TR.

Investigation and assessment of TR severity

TR is frequently identified incidentally during routine echocardiography, often performed for unrelated reasons in asymptomatic patients. In contrast, symptomatic individuals may present with a range of clinical features including fatigue, exertional dyspnoea, peripheral oedema, ascites, gastrointestinal symptoms, and signs of right heart failure. In advanced stages, renal and hepatic dysfunction may also occur (Otto et al. 2021).

Clinical evaluation typically begins with a general practitioner (GP) reviewing the patient's medical history for conditions associated with TR. If TR is suspected, the patient is usually referred to a cardiologist for further assessment. Depending on the severity and underlying mechanism, the cardiologist may then refer the patient to an interventional cardiologist or a cardiothoracic surgeon for consideration of procedural intervention.

Echocardiography remains the gold standard for assessing both the mechanism and severity of TR. Transthoracic echocardiography (TTE) is the primary imaging modality used for initial screening, providing evaluation of valve anatomy and regurgitation severity. Transoesophageal echocardiography (TOE) offers more detailed imaging and is particularly useful when TTE results are inconclusive or suboptimal. In cases where echocardiographic imaging is limited or findings are discordant, additional modalities such as computed tomography (CT) may be used to further clarify the diagnosis and guide management.

Current management of severe, symptomatic TR

In Australia, current treatment options for severe TR include medical therapy, surgical valve repair or replacement via open-heart or minimally invasive approaches, with the latter more recently including, transcatheter tricuspid valve intervention (TTVI).

The majority of patients with TR are managed with medical therapy alone, primarily aimed at symptom relief. Both the American Heart Association/American College of Cardiology (AHA/ACC) and the European Society of Cardiology/European Association for Cardiothoracic Surgery (ESC/EACTS) guidelines recommend the use of diuretics, particularly loop diuretics, to reduce volume overload in patients with signs of right-

sided heart failure (Otto et al. 2021; Praz et al. 2025). However, diuretics do not alter the underlying disease process and have no proven role in preventing or delaying TR progression.

Surgical intervention is recommended in selected cases. The AHA/ACC guidelines support surgery for patients with severe TR, including those with isolated TR due to annular dilation, in the absence of pulmonary hypertension or left-sided heart disease (Otto et al. 2021). Similarly, the ESC/EACTS guidelines recommend considering surgery in patients with severe secondary TR who are symptomatic or have RV dilation or function deterioration, provided there is no severe ventricular dysfunction or pulmonary hypertension (Praz et al. 2025).

Despite these recommendations, surgical intervention is offered to only a small proportion of patients, largely due to high operative risk, multiple comorbidities, and late-stage disease presentation or referral (Latib et al. 2018; Praz et al. 2025). Operative mortality for severe isolated TR is reported to range between 8% and 20% (Otto et al. 2021), contributing to the preference for conservative management in many cases.

The ESC/EACTS guidelines suggest that TTVI should be considered at experienced heart valve centres to improve quality of life and RV remodelling in high-risk patients with symptomatic, severe TR despite OMT in the absence of severe RV dysfunction or pre-capillary pulmonary hypertension (Praz et al. 2025). TTVI technologies are broadly categorised into TTV repair and replacement devices:

- TTV repair includes TEER devices, which approximate valve leaflets to reduce regurgitation, and annular reshaping devices, which aim to restore the normal geometry of the tricuspid annulus.
- TTV replacement involves the implantation of a bioprosthetic valve to replace the native tricuspid valve and was the focus of MSAC application 1799, an application withdrawn prior to the November 2025 MSAC meeting.

Intervention

The intervention proposed in the application is T-TEER using the TriClip system in addition to continued OMT.

T-TEER is a minimally invasive, catheter-based procedure intended to reduce TR by grasping and approximating the tricuspid valve leaflets to improve coaptation. The device is delivered via a transvenous approach and mechanically captures opposing leaflets, thereby reducing the regurgitant orifice area and limiting backward blood flow from the right ventricle to the right atrium during ventricular contraction.

This reconstruction of the valve through tissue approximation is designed to reduce volume overload and improve haemodynamic efficiency, which may help alleviate symptoms and improve functional status.

T-TEER provides a less invasive alternative to surgical repair, particularly for patients considered at high operative risk.

The procedure involves the placement of a permanent implant that remains attached to the valve leaflets, ensuring sustained improvement in their coaptation over time. Acting as a mechanical bridge, the implant secures the grasped leaflets together, thereby maintaining the reduction in regurgitation. The number of implants required depends on the size of the regurgitant orifice and the patient's specific valve anatomy; one or more may be necessary to achieve an effective seal and optimal haemodynamic outcomes. In the TRILUMINATE Pivotal RCT, patients received an average of 2.2 TriClips, with 24.4% requiring 3 clips and 2.9% requiring 4 clips (Sorajja et al. 2023). This is notably higher than the typical number of MitraClips used in transcatheter mitral valve repair (TMVr), where most procedures involve only 1 or 2 clips.

PASC considered whether the forthcoming assessment should be device-specific or device-agnostic and expressed a preference to evaluate the proposed procedure rather than a particular device. PASC noted that an RCT (CLASP II TR trial) is currently underway using the PASCAL Precision system, which has Therapeutic Goods Administration (TGA) approval for tricuspid valve repair, but results have not yet been reported.

Referral and assessment of suitability for T-TEER

Referral for T-TEER is typically initiated by the patient's treating specialist, most commonly a cardiologist, following identification of symptomatic TR that may be suitable for intervention. In some cases, referral may also be initiated by other physicians involved in the patient's care, such as general physicians or heart failure specialists.

Once referred, the patient undergoes a comprehensive evaluation by an MDHT. This team is responsible for determining clinical eligibility and procedural suitability for T-TEER. The assessment includes detailed imaging (e.g. echocardiography, cardiac CT), evaluation of comorbidities, anatomical suitability, and consideration of alternative treatment options. The MDHT also reviews the patient's operative risk and symptom burden to determine whether T-TEER is appropriate, or whether medical management or surgical intervention is more suitable.

PASC discussed whether a cardiac imaging specialist should be a mandatory member of the MDHT and advised that this was unnecessary. PASC noted the current MDHT process appeared to be functioning well, with numerous and varied transcatheter intervention cases reviewed at the same meeting, therefore the requirement of an imaging specialist may not be feasible for isolated cases and add unintended complexity to meeting arrangements.

Procedure setting and delivery of T-TEER

T-TEER is intended to be performed exclusively as an inpatient procedure at specialised cardiac centres, in either public or private hospital settings. These centres must be accredited for structural heart interventions in accordance with national cardiac accreditation criteria, similar to those required for transcatheter aortic valve implantation (TAVI) and MitraClip procedures.

The procedure is performed by accredited specialists – typically interventional cardiologists or cardiothoracic surgeons – who have completed dedicated training in T-TEER, including proctoring and certification by the device manufacturer (e.g. Abbott).[3] A cardiovascular imaging specialist with advanced expertise in structural heart disease is required throughout the procedure to provide continuous imaging guidance. The mean procedure time for T-TEER was 151 minutes in TRILUMINATE Pivotal (Sorajja et al. 2023).

T-TEER is generally conducted under general anaesthesia to optimise TOE imaging, ensure airway control, and maintain patient immobility. However, deep or moderate sedation may be considered in selected patients, depending on clinical circumstances and operator experience.

Imaging plays a central role throughout the procedure. Preprocedural assessment typically includes TTE, TOE, and cardiac CT to evaluate the severity and mechanism of TR, leaflet morphology, and anatomical suitability. During the procedure, real-time TOE is the primary imaging modality used to guide device positioning, leaflet grasping, and confirmation of coaptation. Fluoroscopy is used concurrently to visualise

[3] Cardiac Accreditation Services Limited (CASL) oversees the accreditation of suitably qualified practitioners to perform cardiac procedures including Transcatheter Aortic Valve Implantation (TAVI) and Transcatheter Mitral Valve Repair (TMVr) [https://cardiacaccreditation.org.au/about].

catheter and device movement. In cases where TOE is contraindicated or suboptimal, intracardiac echocardiography (ICE) may be used as an alternative.

PASC advised that the intervention should be restricted to accredited cardiac centres, consistent with the standard practice for other existing structural heart procedures such as TAVI, noting that these high-end interventions require sites with appropriate experience, infrastructure, and capability to ensure safety and quality outcomes.

PASC noted consumer concerns regarding workforce capacity impacting accessibility, noting that the procedure requires advanced training beyond standard practice and carries inherent risks. PASC noted the applicant's clinical experts advised that the main limitation is the availability of interventional echocardiographers, who must interpret complex imaging and guide the procedure in real time. While most major centres in capital cities already have teams experienced in TMVr and are expected to perform T-TEER, some centres still lack adequately trained TOE specialists. The applicant's clinical experts further stated, however, that dedicated interventional echo training programs are addressing this gap, with growing participation from younger clinicians.

PASC noted the applicant's clinical experts advised that the rollout of T-TEER is anticipated to be gradual, starting in accredited tertiary centres with the necessary infrastructure and skilled workforce. Widespread availability in local hospitals is unlikely in the near term. PASC was advised that structural heart programs capable of performing TAVI and transcatheter mitral and tricuspid interventions remain limited, and access will continue to be controlled through accreditation requirements for both sites and individuals to maintain safety and capability standards. The applicant's clinical experts further informed that clinicians who receive training overseas can help support service expansion upon returning to Australia.

Post procedural care and follow up

Following T-TEER, patients typically remain in hospital for short-term monitoring. The duration of inpatient stay may vary depending on individual clinical factors, procedural complexity, and institutional protocols, but is generally shorter than for surgical valve repair. The mean hospital length of stay was 1.6 days in the TRILUMINATE Pivotal trial (Sorajja et al. 2023).

Post-procedural care includes haemodynamic monitoring, assessment for potential complications (e.g. bleeding, arrhythmias, device-related issues), and early imaging to confirm device position and function. TTE is performed prior to discharge to evaluate residual TR, leaflet mobility, and right heart function.

Reintervention may be required in cases of clip detachment, which typically occurs within the first 24 hours post-procedure while the patient is still hospitalised. According to the applicant's clinical expert, detachment rates are higher for T-TEER compared to TMVr, although these rates tend to decline with increased operator experience. In instances of single leaflet detachment, the procedure is generally repeated to reclip the valve leaflets. Complete clip detachment and embolisation is rare but may occur and is managed medically when it does.

Patients are typically discharged on guideline-directed medical therapy for heart failure and arrhythmia management, as appropriate. Antithrombotic therapy may be prescribed based on individual risk factors and procedural outcomes, in accordance with local protocols and clinical guidelines.

Long-term follow-up includes regular clinical review and repeat imaging (every 1 to 2 years) to monitor valve function and assess for progression of TR or other cardiac conditions.

Expected uptake of the technology

Not all patients with severe TR will be clinically indicated or eligible for T-TEER. The application asserts that the proposed population is most consistent with the 'pure AF' subgroup defined in Offen et al. (2022) as patients with severe TR but without significant pulmonary hypertension or left-sided valvular or ventricular dysfunction. Offen et al. (2022) found that 10% of severe TR patients met this definition. Applied to the Australian severe TR population, this equates to approximately 2,932 patients potentially suitable for T-TEER.

The application acknowledged that this estimate excludes some patients, such as those with primary TR or anatomical contraindications, and does not fully match the proposed MBS criteria, but provides a reasonable initial indication of the likely order of magnitude of patients who may be considered for T-TEER in Australia across both public and private healthcare settings.

The application estimated that the uptake of T-TEER would be 50% in the first years of MBS listing, which equates to 1,466 patients. Final estimates will be refined in the Applicant-Developed Assessment Report (ADAR).

Regulatory status

Two T-TEER devices – the TriClip Transcatheter Tricuspid Valve Repair System (Abbott Medical) and the PASCAL Precision System (Edwards Lifesciences) – are included in the Australian Register of Therapeutic Goods (ARTG) (Table 2).

The TriClip system is indicated for patients with severe, symptomatic TR. The PASCAL system is indicated for the repair of the mitral and/or tricuspid valve in patients with clinically significant, symptomatic MR or TR.

Table 2 T-TEER systems included in the ARTG

Product Name	**TriClip Transcatheter Tricuspid Valve Repair System**	**PASCAL Precision System**
Sponsor	Abbott Medical Australia Pty Ltd	Edwards Lifesciences Pty Ltd
ARTG ID	498645 – TriClip G5 Delivery System – Heart Valve Clip[a] 498646 – TriClip G5 Steerable Guide Catheter – Catheter, intravascular, guiding[b]	410289 – PASCAL Precision System – PASCAL ACE Implant System – Heart valve clip 410288 – PASCAL Precision System – Implant System – Heart valve clip 410290 – PASCAL Precision System – Guide Sheath – Heart valve clip
GMDN	57790 Heart valve clip 17846 Catheter, intravascular, guiding	57790 Heart valve clip
Category	Medical Device Class III	Medical Device Class III
Effective Date	8 July 2025	9 June 2023

Product Name	TriClip Transcatheter Tricuspid Valve Repair System	PASCAL Precision System
Functional description	A sterile implantable device intended for the reconstruction of an insufficient tricuspid heart valve and reduction of valve regurgitation through the fixed approximation of the tricuspid valve leaflets. It is typically implanted using a percutaneous clip delivery system guided by echocardiographic and fluoroscopic imaging. It is typically made of implant grade metal alloys with a polyester fabric cover. The disposable clip delivery system is typically included with the tricuspid valve clip. The TriClip G5 Steerable Guide Catheter's primary function is to access the right atrium, maneuver to the target location above the tricuspid valve and position the Delivery System.	The PASCAL Precision System is comprised of the Implant System and Guide Sheath. The Implant System consists of the Loader, Steerable Catheter, Implant Catheter and Implant which comes in two sizes: 10 mm and 6 mm. The 10 mm Implant is referred to as PASCAL Implant and the 6 mm Implant is referred to as PASCAL Ace Implant. The Guide Sheath consists of the Guide Sheath, Introducer and an additional Loader for user convenience.
Intended Purpose	The TriClip G5 System is intended for reconstruction of the insufficient tricuspid valve through tissue approximation. The TriClip G5 System is indicated for patients with severe, symptomatic tricuspid regurgitation.	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.
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.	No specific conditions

Source: Australian Register of Therapeutic Goods, accessed 17 October 2025.
ARTG = Australian Register of Therapeutic Goods; GMDN = Global Medical Device Nomenclature; T-TEER = tricuspid valve transcatheter edge-to-edge repair.
[a] Predecessors of the TriClip Delivery System remain available on the ARTG (444061, 401430, 373218).
[b] Predecessors of the TriClip Steerable Guide Catheter remain available on the ARTG (444062, 401431, 373219).

Regulatory approval of the TriClip system includes a condition requiring submission of final 5-year follow-up data from the TRILUMINATE Pivotal RCT and the bRIGHT EU Post Approval Study (Table 2). In contrast, the PASCAL Precision system was approved without specific conditions. Currently, there are no RCTs comparing PASCAL with OMT in the proposed population. However, the CLASP II TR trial (NCT04097145), which compares T-TEER using the PASCAL system versus OMT alone in patients with symptomatic, severe TR, is underway with primary completion expected in December 2027.

Current funding of the procedure and device

T-TEER is not currently funded under any public reimbursement program in Australia. Limited access is available in the private sector and in selected public hospitals through *ex gratia* funding arrangements supported by private health insurers and Abbott Medical for eligible patients.

Following submission of an ADAR to the MSAC, an application will be lodged for listing the TriClip device on Part A of the Prescribed List of Medical Devices and Human Tissue Products (PL). According to the cost breakdown provided with the application, the cost of the TriClip system is $REDACTED.

The PASCAL Precision System was listed on the PL in March 2025, with use restricted to transvenous mitral valve repair for degenerative (primary) MR under MBS item 38461. Table 3 outlines the PL grouping for the PASCAL system, which includes MitraClip, the only other TEER device currently listed on the PL.

Table 3 TEER systems on the PL

Product Group	Product Sub Group	Billing Code	Benefit	Product Name	Sponsor
08.17.02 – Mitral Valve Repair	08.17.02.01 – Leaflet	SJ453	$26,386	MitraClip System	Abbott Medical Australasia Pty Ltd.
		SJ460	$26,386	MitraClip G4 System	Abbott Medical Australasia Pty Ltd.
		EL069[a]	$23,104	PASCAL Precision System (PASCAL Implant and PASCAL ACE Implant)	Edwards Lifesciences Pty Limited

PL = Prescribed List of Medical Devices and Human Tissue Products; TEER = transcatheter edge-to-edge repair.
a Suffix 'DMR only', where DMR is degenerative (primary) mitral valve regurgitation. This billing code also had a condition applied: PL reimbursement is restricted to the use of the devices in the procedure described under MBS item 38461, meaning transcatheter mitral valve repair (TMVr) in patients with DMR.
Source: Prescribed List, effective from 1 November 2025.

PASC noted that the proposed PL benefit for the TriClip system ($REDACTED) is higher than for the MitraClip system (current PL benefit $26,386). PASC was advised that the higher benefit reflects the higher average number of clips required for each T-TEER procedure compared with mitral TEER (an average of 2.2 clips versus 1.5–1.6 clips). It also reflects the higher rate of single leaflet detachment occurring within 48 to 72 hours, which can lead to an additional procedure for re-clipping. Currently, for reclipping procedures performed with TriClip, any additional devices needed are fully covered ex gratia *by the sponsor.*

Comparator(s)

The nominated comparator to T-TEER in the proposed population is continued OMT alone. While surgical repair or replacement is included in international guidelines, it is rarely offered in practice due to the high operative risk associated with advanced age, multiple comorbidities, and late-stage presentation or referral (Latib et al. 2018).

According to the ESC/EACTS and AHA/ACC guidelines, diuretics remain the cornerstone of medical management for patients with TR and right heart failure (Praz et al. 2025; Otto et al. 2021). Additional therapies are tailored to individual comorbidities. For example, patients with secondary TR may receive treatment directed to the underlying cause of heart failure, such as pulmonary vasodilators for elevated pulmonary pressures, guideline-directed therapy for heart failure with reduced ejection fraction, or rhythm control strategies for AF. Aldosterone antagonists may be beneficial in mitigating the effects of renin-angiotensin-aldosterone system activation, particularly in the context of hepatic congestion. However, the effectiveness of medical therapy is limited in many patients due to comorbidities such as 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).

The application acknowledged that TTV replacement may represent a potential near-market comparator to T-TEER. However, PASC previously noted that the anatomical and pathological profiles of patients suitable for TTV repair differ from those appropriate for TTV replacement (PICO confirmation for MSAC application 1799). Furthermore, within the clinical management algorithm for patients with severe, symptomatic TR, TTV replacement is generally considered only for those who are not suitable candidates for T-TEER.

PASC considered that continued OMT alone as the nominated comparator is appropriate. While surgery is a potential comparator, it is associated with high complication and mortality rates and is rarely performed in Australia for isolated TR. TTV replacement was considered inappropriate as it targets a different patient population, and MSAC application 1799 for TTV replacement was withdrawn.

Outcomes

The outcomes relevant to the assessment of T-TEER are summarised in Table 4. Procedural and late safety events should be captured in the analysis as both must be factored into clinical decision making, especially given the elderly, often anticoagulated patient population. Patient-reported outcomes are important to demonstrate the effectiveness of T-TEER 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.

Table 4 Outcomes relevant to the assessment of T-TEER

Outcome type	Outcome
Safety	Major CV events (MI, stroke, CV death) Severe bleeding Major access site and vascular complications Major cardiac structural complications (e.g. coronary structure perforation) Conversion to surgery New arrhythmia or conduction disorder requiring permanent pacing New onset renal failure Endocarditis requiring surgery TV reintervention (percutaneous or surgical); explant Device-related events (e.g. detachment, embolisation, thrombosis)
Efficacy/effectiveness	Mortality (all-cause, CV) Hospitalisation for heart failure Change in TR severity/grade QoL using disease-specific (e.g. KCCQ) and generic (e.g. SF-36) tools Health status (NYHA functional class, 6MWT) Change in medical therapy (dose, frequency, type)
Healthcare resources (including patient OOP costs)	Cost of T-TEER prosthesis and other consumables Cost to deliver T-TEER 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 the PBS
Total cost to private health insurers and hospitals	Total cost to the PL for T-TEER prosthesis and changes in use of other prostheses Total cost of hospitalisation for T-TEER, management of complications and reinterventions

CV = cardiovascular; KCCQ = Kansas City Cardiomyopathy Questionnaire; NYHA = New York Heart Association; MBS = Medicare Benefits Schedule; MI = myocardial infarction; 6MWT = 6-minute walk test; OOP = out-of-pocket; PBS = Pharmaceutical Benefits Scheme; PL = Prescribed List of Medical Devices and Human Tissue Products; QALY = quality-adjusted life year; QoL = quality of life; SF-36 = Medical Outcomes Study 36-item Short Form Health Survey; TR = tricuspid regurgitation; T-TEER = tricuspid valve transcutaneous edge-to-edge repair; TV = tricuspid valve.

The key evidence cited in the application to support the clinical claims (listed in the Proposed economic evaluation of this document) is the TRILUMINATE Pivotal RCT, in which 572 subjects were randomised 1:1 to T-TEER plus OMT or OMT alone. Study participants were followed for 1 year for the primary endpoint and 2 years for additional secondary endpoints, with planned follow-up annually to 5 years (study

completion expected in April 2029). Following completion of the 12-month primary endpoint, crossover from the control arm to receive the T-TEER was permitted.

The Tricuspid Valve Academic Research Consortium (TVARC) advised that the duration of study follow up must be sufficient to ascertain whether device durability is acceptable for the intended patient population (Hahn et al. 2023). Published follow-up is currently to 2 years for the TRILUMINATE Pivotal RCT. Longer term follow-up is available from the TRILUMINATE single arm trial (N=98), which followed participants for up to 3 years.

All individual safety and efficacy outcomes in Table 4 appear to have been captured in the TRILUMINATE Pivotal RCT. According to the protocol (Sorajja et al. 2023, supplementary material), the primary outcome measure for TRILUMINATE Pivotal was a hierarchical composite at 1 year (expressed as a win ratio) that included: time to all-cause death or tricuspid valve surgery; number of heart failure hospitalisations; an improvement of at least 15 points in Kansas City Cardiomyopathy Questionnaire overall summary (KCCQ-OS) from baseline. Powered secondary endpoints were: TR reduction to moderate or less at 30 days; freedom from major adverse events (MAE)[4] at 30 days; change in KCCQ at 12 months; change in Six-Minute Walk Test (6MWT) at 12 months.

PASC noted that the proposed outcomes are consistent with those reported in the pivotal clinical trial and are appropriate for assessing the safety and effectiveness of this intervention.

Clinical management algorithms

The current clinical management algorithm for patients with severe, symptomatic TR despite OMT is shown in Figure 1. Patients undergo a thorough assessment to determine eligibility for TR intervention. This process typically includes:

- initial clinical evaluation conducted by a GP, involving review of the patient's medical history for conditions commonly associated with TR, such as heart failure and other comorbidities
- a series of imaging studies to assess valve structure and TR severity
  - TTE is used as a screening tool to evaluate valve anatomy and the degree of regurgitation
  - TOE provides detailed imaging to confirm the diagnosis, especially when TTE results are inconclusive
  - CT assesses anatomical suitability for interventions, if applicable
- collaborative MDHT assessment to determine the patient's overall risk, anatomical considerations, and appropriateness for intervention.

The MDHT may assess a patient's surgical risk using one of various validated tools, including the EuroSCORE, the Society of Thoracic Surgeons (STS) Risk Score, and the TRI-SCORE system. However, as noted in the PICO confirmation for MSAC application 1799, PASC has previously raised concerns regarding the reliability of these tools in this specific patient cohort.

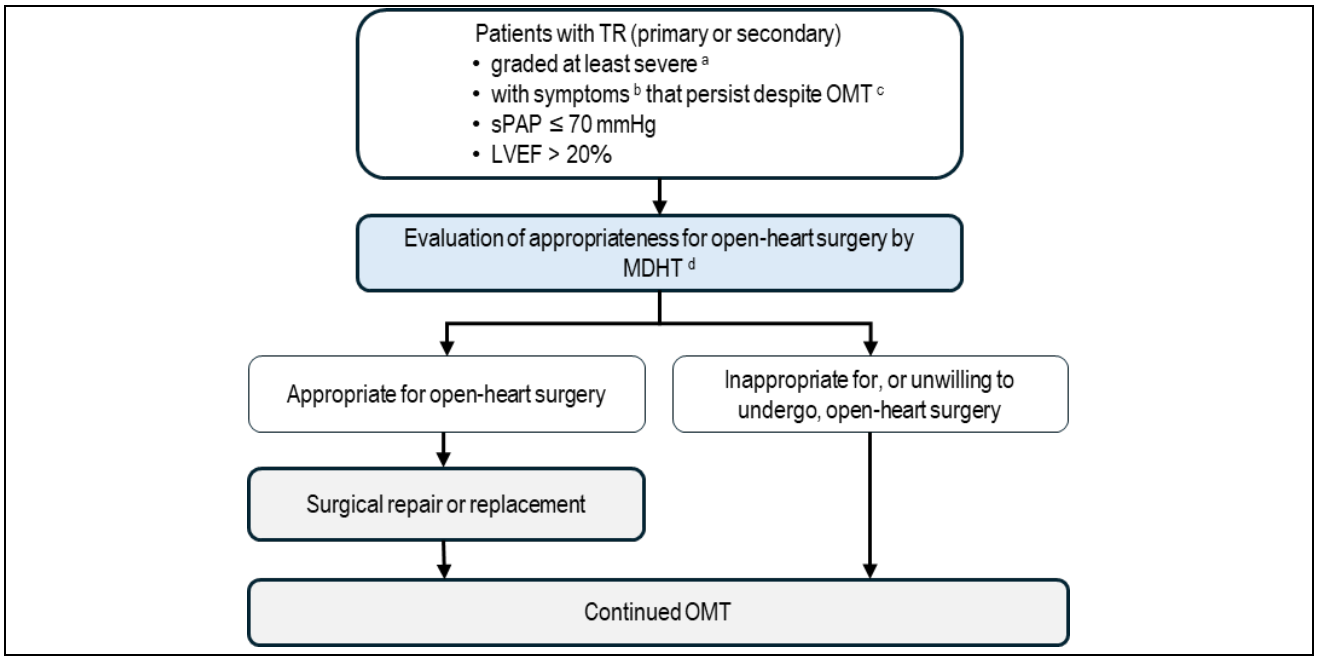
Surgical intervention may be appropriate for a select group of patients with severe, symptomatic TR, particularly when concomitant cardiac conditions warrant open-heart surgery. Among those deemed suitable for surgery, a proportion may decline the procedure or not be offered it due to surgeon reluctance, given the high morbidity and mortality associated with isolated tricuspid valve surgery.

[4] Components of the MAE were: CV mortality; new onset renal failure; endocarditis requiring surgery; non-elective CV surgery for device-related adverse events post index procedure.

Patients who are unsuitable for open-heart surgery or who decline it, the majority continue on OMT alone, supported by specialist care, but often experience suboptimal clinical outcomes and poor long-term prognosis. Patients managed with OMT require regular monitoring of weight, blood pressure, and symptoms, along with routine blood tests to assess renal function and electrolyte balance.

For individuals with a life expectancy of less than one year or those with significant frailty, medical therapy remains the preferred approach, given the limited evidence supporting transcatheter interventions in this population (Rahgozar et al. 2021).

Figure 1 Clinical management algorithm for patients with severe TR: current practice without MBS funding of T-TEER



LVEF = left ventricular ejection fraction; MBS = Medicare Benefits Schedule; MDHT = multidisciplinary heart team; OMT = optimal medical therapy; sPAP = systolic pulmonary artery pressure; TR = tricuspid regurgitation; T-TEER = tricuspid valve transcatheter edge-to-edge repair.
Note: Uptake of T-TEER in the private setting is currently limited to *ex gratia* support from private health insurers or to self-funded patients.
[a] Severity determined by echocardiography using American Society of Echocardiography grading.
[b] Symptomatic = NYHA functional class II, III or ambulatory IV.
[c] OMT refers to stable oral diuretic therapy at a minimum.
[d] Patients are considered for surgery by an MDHT, combining surgical risk assessment, frailty, major organ dysfunction and procedure-specific impediments.

The proposed clinical management algorithm incorporating MBS-funded T-TEER is illustrated in Figure 2.

The introduction of MBS funding for T-TEER is expected to increase procedural uptake, which is currently limited across both public[5] and private healthcare settings in Australia. The Ratified PICO confirmation for MSAC application 1799 noted that there was some use of TTV repair devices (the PASCAL Precision System, the TriClip system) in the public healthcare system in Australia and but limited use in the private setting.

Access to T-TEER is proposed to be restricted to patients who can attend accredited heart centres staffed by appropriately trained and credentialed specialists. Candidacy for T-TEER is considered by the MDHT and determined by a combination of anatomical, functional, and clinical factors. The procedure is most appropriate for patients with preserved leaflet anatomy that permits secure leaflet grasping, particularly in

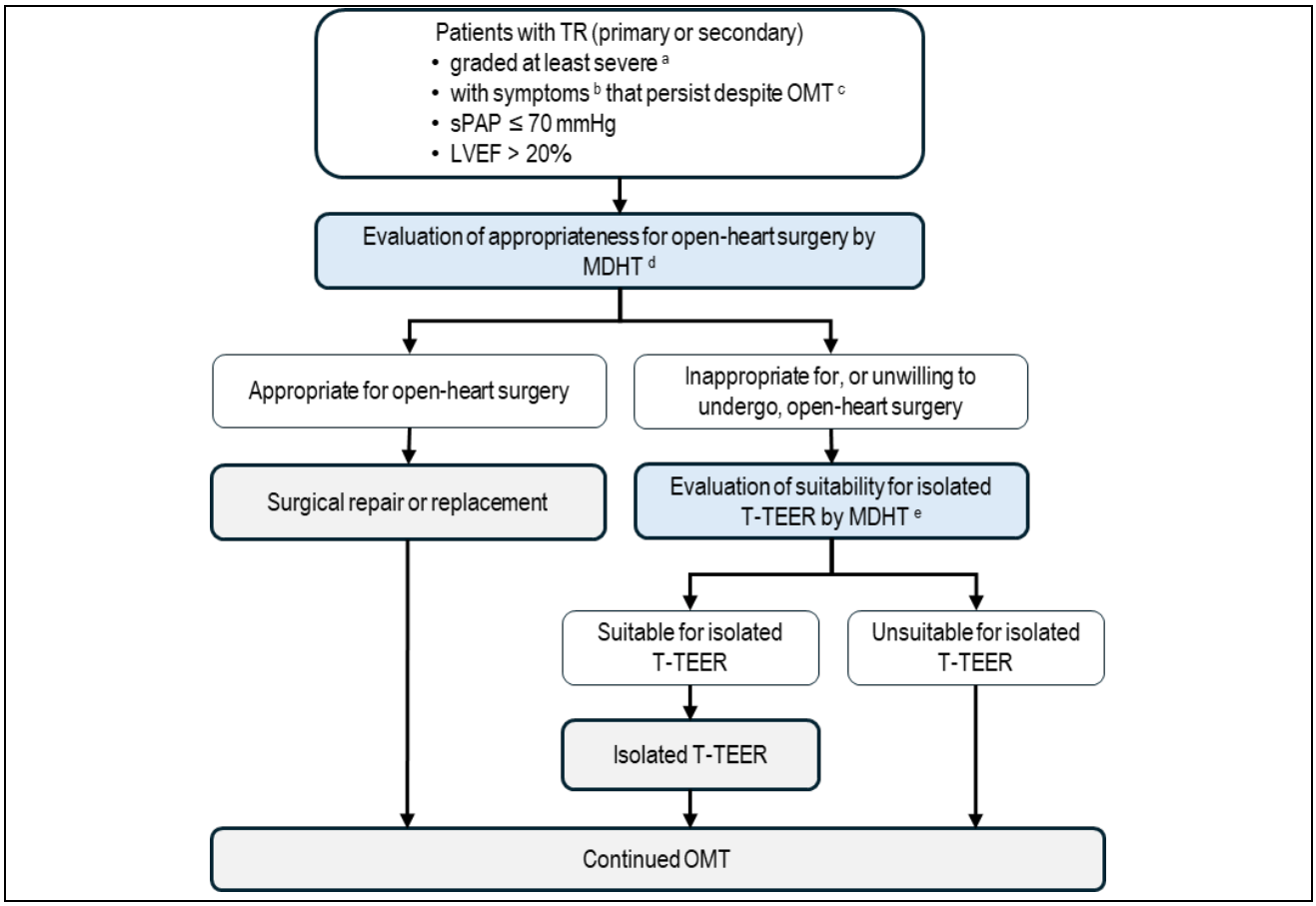
[5] Patients admitted to a public hospital can elect to be treated as a private patient. Therefore, there can be private billing of T-TEER in public hospitals certified to deliver this procedure. T-TEER is not included in the current clinical management algorithm as only a small number of patients may receive the intervention through *ex gratia* funding from private health insurers or via self-funding.

cases of modest annular dilation, small coaptation gaps, and absence of interfering intracardiac leads (e.g. pacemaker or implantable cardioverter defibrillator.

Privately funded TTV replacement may be a viable option when leaflet morphology precludes TTV repair (such as using T-TEER); for example, in the presence of short, severely calcified, fibrotic, degenerated, or retracted leaflets. It is also considered when annular dilation is extreme or coaptation gaps are too large for repair devices to achieve effective leaflet approximation (Nagraj et al. 2022). Despite these indications, T-TEER remains the preferred approach due to its more favourable safety profile. As previously noted, MSAC application 1799 was withdrawn before MSAC consideration.

Patients who are not suitable for T-TEER continue on OMT alone, though this approach is associated with suboptimal clinical outcomes and poor long-term prognosis.

Figure 2 Clinical management algorithm for patients with severe TR: proposed practice with MBS funding of T-TEER



LVEF = left ventricular ejection fraction; MBS = Medicare Benefits Schedule; MDHT = multidisciplinary heart team; OMT = optimal medical therapy; sPAP = systolic pulmonary artery pressure; TR = tricuspid regurgitation; T-TEER = tricuspid valve transcatheter edge-to-edge repair.

[a] Severity determined by echocardiography using American Society of Echocardiography grading.

[b] Symptomatic = NYHA functional class II, III or ambulatory IV.

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

[d] Patients are considered for surgery by an MDHT, combining surgical risk assessment, frailty, major organ dysfunction and procedure-specific impediments.

[e] Patients are considered for T-TEER by an MDHT based on a detailed assessment of comorbidities and expected benefits.

PASC considered that although T-TEER may currently be used to a limited extent in the private setting, it is not established practice and should not be included in the current clinical management algorithm. Otherwise, PASC considered that the current clinical management algorithm is appropriate.

PASC also considered that the proposed algorithm is suitable, provided that TTV replacement, not being publicly funded, is not included as a potential treatment option for the proposed population, as the related MSAC application has been withdrawn.

The application stated that resource utilisation prior to T-TEER will remain consistent between the current and proposed clinical management pathways.

Following T-TEER, patients will continue to receive OMT, with medication regimens adjusted as needed by their treating physician. According to the application, the primary difference in healthcare resource utilisation between T-TEER and OMT alone is the requirement for follow-up TTE (prior to discharge, and ongoing imaging every 1 to 2 years post-procedure).

Proposed economic evaluation

The clinical claim made in the application was that T-TEER using the TriClip System plus OMT is superior with respect to efficacy (mortality, hospitalisation for heart failure, TR severity, and quality of life) and inferior with respect to safety (procedural complications) when compared to OMT alone.

Based on the application's clinical claims of **superior efficacy** and **inferior safety**, a cost-utility analysis (CUA) is likely appropriate (Table 5).

Table 5 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[a]	Noninferior[b]	Superior
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	**? Likely CUA**
Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior[b]	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.
a. 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.
b. An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence.

By definition, T-TEER plus OMT will be associated with additional costs relative to the nominated comparator of OMT alone. Additional costs include the costs of the T-TEER prosthesis, procedural-based implantation costs including the cost of operating rooms and surgical staff, and post-implantation hospitalisation costs.

The cost breakdown accompanying the application stated that the overall cost per patient of providing T-TEER using the TriClip system was approximately $REDACTED:

- device cost $REDACTED
- MBS fees $2,903 (pre-procedural, intraoperative and post-procedural, including anaesthesia and imaging)
- hospital-associated costs $14,624.

PASC agreed that a cost-utility analysis is appropriate, as the applicant is claiming superior efficacy but inferior safety.

PASC advised that the economic outcomes will be critical in the assessment, particularly the need to capture downstream costs such as reintervention and the requirement for additional devices.

PASC considered that the proposed device benefit of $REDACTED on the PL should apply to the procedure as a whole, regardless of the number of clips used, consistent with pricing for other structural heart interventions.

Proposal for public funding

MBS service

The application proposed the creation of a new MBS item for isolated T-TEER performed using the TriClip system (Box 1). The proposed descriptor specifies using the TriClip system on the basis that it is currently the only T-TEER device supported by RCT evidence comparing its use to OMT alone. In contrast, the CLASP II TR RCT evaluating the PASCAL system against OMT is not expected to reach primary completion until December 2027.

The patient population outlined in the proposed item descriptor is broadly consistent with that of the TRILUMINATE Pivotal trial, which evaluated the TriClip system. However, the descriptor omits several key eligibility criteria used in the trial, including: age 18 years or older, absence of severe uncontrolled hypertension, intermediate or greater estimated surgical risk for tricuspid valve intervention, and a reasonable likelihood of achieving moderate or less residual TR following T-TEER. Additionally, the descriptor does not define OMT or specify the required duration of stable OMT prior to intervention. Nonetheless, the application stated that an MDHT would be responsible for assessing each patient's overall risk profile, anatomical suitability, and candidacy for T-TEER.

The application advised that the MDHT should include, at a minimum, an interventional cardiologist or cardiothoracic surgeon, along with a specialist or consultant physician who is not the proceduralist. The applicant's clinical expert noted that while the involvement of a cardiovascular imaging specialist is beneficial, it should be considered desirable rather than mandatory. Two new MBS items have been proposed for attendance at T-TEER case conferences (Box 2), based on MBS items 6082 and 6084 for attendance at transcutaneous mitral valve repair (TMVr) case conferences.

The application proposed formal accreditation of the centre where T-TEER is performed and the heart specialists who perform the procedure, comparable to the accreditation requirements for TAVI and TMVr.

Similar to the existing MBS items for TMVr (MBS items 38461 and 38463), the proposed descriptor for the new T-TEER item includes intraoperative diagnostic imaging to cover both fluoroscopy and TOE. These

modalities are used throughout the procedure to guide implantation and to confirm appropriate positioning and function of the implant(s).

Current MBS items for TOE do not reflect the complexity or specialised expertise required for structural heart interventions such as T-TEER. Broader consideration may be warranted for the development of new MBS items that better align with the procedural demands and training requirements of these advanced imaging roles.

In addition, ICE is increasingly being adopted internationally as the preferred imaging modality for T-TEER and similar procedures, particularly in cases where TOE is contraindicated or suboptimal. At present, no dedicated funding model exists for ICE, but this may need to be considered as utilisation of the technology expands.

The proposed item descriptor for T-TEER does not specify a limit on the number of services per patient. This contrasts with the existing TMVr items (MBS 38461 and 38463), which restrict access to one procedure every 5 years. However, clinical experience indicates that some patients may require repeat interventions within a shorter timeframe due to progressive underlying disease, even when leaflet anatomy is not the limiting factor. In the mitral space, the 5-year restriction has posed challenges for patients who would benefit from re-intervention, typically within 2 to 3 years. The applicant's clinical expert advised that, if a time-based restriction were to be considered, a 2-year interval would be more clinically appropriate.

In addition to disease progression, reintervention may also be required in cases of clip detachment, which typically occurs within the first 24 hours post-procedure while the patient is still hospitalised. In such cases, the procedure is repeated to reclip the valve leaflets. The applicant has indicated that, where reintervention occurs within the same episode of care, the reclipping device and procedure are not charged separately. However, this is a discretionary policy and may not apply in all circumstances. It is therefore important to recognise that the proposed MBS item may be used more than once per patient, and funding arrangements should account for the possibility of repeat procedures, particularly in the early post-operative period.

PASC noted that the applicant's proposed MBS item descriptor was device-specific. The applicant explained that they are currently the only company with robust clinical evidence for T-TEER and highlighted parallels with the initial TMVr application, where MSAC previously adopted a brand-specific descriptor. However, PASC noted that clinicians generally prefer a device-agnostic listing, as other TEER technologies are expected to emerge, and a broader approach would provide greater flexibility and future-proofing. PASC advised the applicant to present the available evidence – recognising that their device is the only one with RCT data at present – to justify a device-specific listing, while noting that MSAC will ultimately determine whether this is appropriate.

PASC considered whether the components of OMT should be specified in the item descriptor and advised that this was unnecessary. PASC noted that OMT primarily consists of diuretics, and there is little evidence that other therapies significantly impact outcomes. It can be assumed that clinicians have provided appropriate medical management before T-TEER is considered.

PASC discussed whether a time restriction is needed for repeat T-TEER procedures, noting the high mortality in this population (17% at 2 years and 27% at 3 years in the pivotal trial). While the TMVr item currently has a 5-year exclusion period, PASC noted advice from the applicant's clinical expert that a small subset of patients may deteriorate earlier due to underlying disease, and that reintervention in these cases could provide repeated clinical benefit. PASC noted that early reintervention for single leaflet detachment

within 48–72 hours is a separate issue from repeat T-TEER months or years later. PASC was unaware of evidence demonstrating clinical benefit from repeat procedures in this elderly, high-mortality population and advised that such evidence would be necessary to justify a shorter exclusion period. Without this, patients may face the cost and risks without clear benefit. PASC advised that the restriction should remain at 5 years – consistent with TMVr – unless clinical and economic evidence supports reducing it to 2 years.

PASC heard from the applicant's clinical experts that removing the term 'isolated' from the proposed descriptor would allow patients requiring both tricuspid and mitral valve repair to undergo both procedures during a single admission. The experts stated that performing the procedures concurrently is more efficient and avoids a second, subsequent hospital stay, anaesthetic, and other additional risks and costs associated with 2 separate procedures. The experts claimed that 20–30% of patients present with disease affecting both valves, and around 25% of current T-TEER procedures are performed as part of combined interventions. These patients are often older and frail, making two separate procedures a significant burden. Performing both at once typically adds only 20–30 minutes to the procedure time compared with repeating the entire process later.

PASC acknowledged this separate but related issue and advised that patients requiring repair of both valves represent a distinct population and therefore would need a separate PICO set, with supporting evidence and an appropriate fee. This population could be considered in a future application; however, the current application should remain limited to isolated tricuspid valve repair, consistent with the key clinical trial.

PASC considered a policy question on whether tricuspid valve repair and valve replacement should be combined into a single item. PASC advised that this issue is not relevant at present, as MSAC application 1799 for TTV replacement has been withdrawn. Furthermore, the procedures are technically distinct, and the patient populations differ anatomically; therefore, they should be considered separately.

The proposed fee for the T-TEER service is the same as that for TMVr using the MitraClip system (MBS item 38463). The application asserts that both procedures are comparable in terms of complexity, duration and resource utilisation. However, while the TriClip procedure avoids transseptal puncture, it presents greater technical challenges in terms of device steering and imaging. Additionally, T-TEER often requires the placement of more clips than TMVr. As a result, T-TEER is generally more technically demanding, takes longer to perform, and requires a higher level of procedural expertise. Consequently, only a subset of TMVr operators is expected to perform T-TEER.

PASC discussed the proposed MBS item fee for the T-TEER procedure and advised that it should remain the same as for TMVr. While T-TEER generally takes longer and procedure times vary considerably, PASC noted the advantages of maintaining consistency with established precedents, including MSAC application 1799 for TTV replacement before it was withdrawn, where the proposed fee was in line with TMVr despite that procedure being more complex than T-TEER and TMVr.

PASC discussed whether current reimbursement adequately reflects the complexity of real-time structural imaging such as interventional TOE, which is an integral component of the procedure. This type of TOE is significantly more time-consuming and requires a higher level of skill and training than standard intraprocedural or diagnostic TOE. PASC was advised that relevant professional societies are advocating for a dedicated MBS item for structural interventional TOE, specifically for echocardiologists and anaesthetists trained to perform it. Any new item would need to account for local variations in practice. The applicant's clinical experts highlighted an existing inequity: anaesthetists can charge on a time basis for the 2–3 hour procedure, whereas echocardiologists can only claim the standard TOE fee intended for a much shorter procedure such as left atrial appendage closure (typically 20–40 minutes). PASC acknowledged this as an important issue but noted it falls outside the remit of the current application.

Box 1 New MBS item descriptor proposed in the application

Category 3 – THERAPEUTIC PROCEDURES
Transcatheter edge to edge repair (TEER), by transvenous techniques, for permanent coaptation of tricuspid valve leaflets using one or more TriClips™ *[generic alternative: 'tissue approximation implants']* including intraoperative diagnostic imaging if: (a) the patient has: (i) severe or greater tricuspid regurgitation, as determined by echocardiography; *and* (ii) symptoms (New York Heart Association functional class II ~~or greater~~*, III or ambulatory IV*) despite optimal medical therapy; *and* (ii) left ventricular ejection fraction of *more than* 20% ~~or more~~; *and* (iii) systolic pulmonary artery pressure ~~of less than~~ *no higher than* 70mmHg, and (b) the patient is deemed suitable for *isolated T-*TEER by a qualified multidisciplinary heart team, following a detailed assessment of comorbidities and expected benefits; and (c) the service is performed: (i) by an accredited interventional cardiologist or cardiothoracic surgeon trained and certified by the *T-*TEER accreditation committee; (ii) in a hospital accredited by the *T-*TEER accreditation committee to ensure appropriate facilities, personnel, and postoperative care; and (d) the service is not associated with a service to which item 38516, 38517 applies*, and has not been provided to the patient in the previous 5 years* (H) Multiple Operation Rule (Anaes.) (Assist.)
Fee: *[not less than]* $1,670.80 **Benefit**: 75% = $1,253.10

Fees are based on MBS items 38461 and 38463 for TMVr, effective 1 November 2025.
Suggested amendments from PASC are shown in ~~strikethrough~~ and *blue italics*.

Box 2 New MBS item descriptors proposed in the application for T-TEER case conferences

Category 1 – PROFESSIONAL ATTENDANCES
MBS item YYYY Attendance at a T-TEER suitability case conference, by a cardiothoracic surgeon or an interventional cardiologist, to coordinate the conference, if: (a) the attendance lasts at least 10 minutes; and (b) the surgeon or cardiologist is accredited by the T-TEER accreditation committee to perform the service Applicable once per patient per lifetime
Fee: $59.40 **Benefit**: 75% = $44.55 85% = $50.50 Extended Medicare Safety Net Cap: $178.20
MBS item ZZZZ Attendance at a T-TEER suitability case conference, by a specialist or consultant physician, other than to coordinate the conference, if the attendance lasts at least 10 minutes Applicable once per patient per lifetime
Fee: $44.30 **Benefit:** 75% = $33.25 85% = $37.70 Extended Medicare Safety Net Cap: $132.90

Fees are based on MBS items 6082 and 6084 for TMVr suitability case conferences, effective 1 November 2025.

Medical device

The proposed cost of the TriClip system ($REDACTED) is approximately REDACTED% higher than the PL benefit for the MitraClip system (see Table 3).

The applicant confirmed that this cost remains fixed regardless of the number of clips used during the procedure, which is consistent with the pricing model for MitraClip.

Inclusion of T-TEER systems on the PL would require the creation of a new Group for tricuspid valve repair within Subcategory 08.17 – Catheter Delivery – of the Cardiac Category.

Summary of public consultation input

PASC noted and welcomed consultation input from 7 organisations and 1 individual medical professional. The 7 organisations that submitted input were:

- Hearts4heart
- Heart Support Australia
- Medtronic Australasia Pty Ltd (Medtronic)
- Edwards Lifesciences Pty Ltd (Edwards)
- Private Healthcare Australia (PHA)
- The Cardiac Society of Australia and New Zealand (CSANZ)
- Australasian Society of Medical Perfusionists (ASMP)

Consultation input was largely supportive of public funding for TEER for the treatment of severe TR using the TriClip device. Some submissions raised concerns, predominantly in relation to the device-specific nature of the proposed MBS item descriptor and the potential financial impact on the health system.

Consumer Experience

Consumer input, particularly from Hearts4heart and Heart Support Australia, strongly emphasised the significant burden that severe TR places on individuals and their families. Consumers described symptoms such as extreme fatigue, breathlessness, and reduced ability to participate in daily activities, which can lead to social isolation and diminished mental health. Both organisations highlighted that current medical management options are limited and often ineffective for this patient group.

Consumers reported that access to TEER using the TriClip device offers substantial improvements in quality of life, including increased independence, reduced hospitalisations, and the ability to resume normal activities. Personal stories shared by patients illustrated rapid recovery and meaningful improvements in daily functioning following the procedure. Consumer groups advocated for public funding to access this minimally invasive therapy, noting its potential to address a significant unmet clinical need and improve long-term outcomes for Australians living with severe TR.

Benefits and Disadvantages

The consultation input identified several important benefits associated with public funding for TEER using the TriClip device. Stakeholders emphasized that TEER provides a minimally invasive treatment option for patients with severe TR who are at high risk for surgery and have limited alternatives. This was seen as addressing a significant unmet clinical need. Professional and industry input described improvements in quality of life, independence, and reduced hospitalisations following TEER, with patients able to resume

normal activities and experience rapid recovery. Professional and industry stakeholders also noted that public funding would align Australia with international best practice and ensure equitable access to advanced therapies.

However, some disadvantages and concerns were raised. PHA expressed apprehension about the potential for underestimated costs and higher-than-anticipated utilisation, which could have a significant financial impact on both the health system and private health insurers. PHA noted that while short-term benefits are clear, the long-term survivorship and comparative effectiveness of TEER versus OMT remain to be fully established. Medtronic, Edwards, and CSANZ raised concerns about the proposed MBS item descriptor being limited to a single device (TriClip), advocating instead for a device-agnostic approach to ensure clinical flexibility, foster competition, and avoid inequities in patient access.

Population, Comparator (current management), and Delivery

Consultation input was supportive of the proposed population, with most organisations agreeing that the target group—patients with severe TR who are symptomatic despite treatment with OMT—is appropriate and consistent with clinical guidelines. Consumer groups and professional bodies highlighted the significant unmet need for this population and endorsed the inclusion criteria outlined in the application.

Consultation input also agreed with the proposed comparator of OMT, noting that current management options are limited and often ineffective for this patient group.

Regarding delivery, consultation input supported the proposed approach, emphasising the importance of MDHT assessment and the need for accredited facilities and trained operators.

MBS Item Descriptor and Fee

Medtronic, Edwards, and CSANZ strongly disagreed with the item descriptor being limited to a single device (TriClip). These stakeholders advocated for a device-agnostic descriptor, arguing that this approach would maintain clinical flexibility, foster competition, and ensure equitable access to all TGA-approved TEER technologies. They noted that international best practice and recent MSAC precedents support device-neutral item descriptors for similar interventions.

Regarding the proposed fee, most professional and industry inputs considered it appropriate, noting that it aligns with the existing fee for transcatheter mitral valve repair procedures. PHA highlighted concerns about the accuracy of cost projections in the application, referencing previous cardiac interventions where actual expenditure significantly exceeded initial estimates. They urged MSAC and the department to closely monitor real-world outcomes and financial impacts if TEER is publicly funded.

PASC noted that public consultation feedback from individual clinical professionals was limited but feedback from the 7 organisations was uniformly supportive of an MBS listing for T-TEER. The most common theme was a preference for an MBS listing that is device-agnostic. Consumer organisations also highlighted that this is an area of significant unmet need and expressed strong support for its approval.

Next steps

The applicant confirmed that an applicant-developed assessment report (ADAR) will be submitted.

Applicant Comments on Ratified PICO

The applicant had no comment.

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