

MSAC application 1812

**Transcatheter Edge-To-Edge Repair
(TEER) for the treatment of severe
tricuspid regurgitation (TR) using the
TriClip device**

Application for MBS eligible service or health technology

HPP Application number:

HPP200327

Application title:

Transcatheter Edge-To-Edge Repair (TEER) for the treatment of severe tricuspid regurgitation (TR) using the TriClip device

Submitting organisation:

ABBOTT MEDICAL AUSTRALIA PTY LTD.

Submitting organisation ABN:

73080212746

Application description

Succinct description of the medical condition/s:

Your heart has four valves, and the tricuspid valve is one of them. It sits between the right upper chamber (atrium) and the right lower chamber (ventricle). Its job is to make sure blood flows in the right direction.

In tricuspid regurgitation, this valve doesn't close properly. That means some blood leaks backward into the upper chamber instead of moving forward to the lungs.

When this leakage is severe, it can cause serious problems. Over time, severe leakage makes the heart work harder. This can lead to heart failure, liver problems, or other complications if not treated.

Succinct description of the service or health technology:

Transcatheter Edge to Edge Repair (TEER) with TriClip is a minimally invasive procedure used to treat severe tricuspid regurgitation, where a heart valve leaks and causes blood to flow backward. A small clip is placed on the valve through a vein to help it close better and reduce leakage. For patients who are high-risk for open-heart surgery and don't respond well to medication, TEER may be the only treatment option to improve heart function and quality of life.

Application contact details

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

Applicant

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

Organisation

Applicant organisation name:

ABBOTT MEDICAL AUSTRALIA PTY LTD.

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?

Yes

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

Prescribed List

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

New

Relevant MBS items

What is the type of service or health technology?

Therapeutic

PICO set

PICO set for Transcatheter Edge-To-Edge Repair (TEER) for the treatment of severe tricuspid regurgitation (TR) using the TriClip device

Population

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

The proposed population for whom listing of TEER is sought on the Medicare Benefits Schedule includes patients with severe TR who are symptomatic (NYHA Functional Class II, III or ambulatory class IV) despite treatment with OMT with systolic pulmonary artery pressure (sPAP) <70mmHg and left ventricular ejection fraction (LVEF) >20% and are deemed by a qualified multidisciplinary heart team to be suitable for TEER.

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

Tricuspid valve regurgitation

Intervention

Name of the proposed health technology:

Transcatheter edge-to-edge repair (TEER) using TriClip™

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

The nominated comparator to TEER in the proposed population is continued OMT alone. The comparator to TEER in the pivotal study (TRANSLUMINATE Pivotal) is OMT. Whilst surgery is included in guidelines, only selected patients are currently being offered surgical intervention, mainly due to high operative risk owing to a multitude of comorbidities and late presentation or referral for intervention (Latib 2018).

Outcomes

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

Please refer to PICO set document - Outcomes section.

Proposed MBS items

Proposed item:

AAAAA

MBS item number (where used as a template for the proposed item):

NA

Category number:

THERAPEUTIC PROCEDURES

Category description:

SURGICAL OPERATIONS

Proposed item descriptor:

Transcatheter edge to edge repair (TEER), by transvenous techniques, for permanent coaptation of tricuspid valve leaflets using one or more Triclips™" including intraoperative diagnostic imaging if:

- (a) the patient has:
 - (i) severe or greater tricuspid regurgitation, as determined by echocardiography;
 - (ii) symptoms (New York Heart Association functional class II or greater) despite optimal medical therapy;
 - (ii) left ventricular ejection fraction of 20% or more;
 - (iii) systolic pulmonary artery pressure of less than 70mmHg, and
- (b) the patient is deemed suitable for 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 TEER accreditation committee;
 - (ii) in a hospital accredited by the 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

(H)

Multiple Operation Rule

(Anaes.) (Assist.)

Proposed MBS fee:

\$1,670.80

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

\$REDACTED

Please specify any anticipated out of pocket expenses:

\$0.00

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

TEER is not funded in Australia at present. (Note. Except for limited ex-gratia funding by the private health insurers for the eligible patients in private sector as well as in public hospitals.)

Claims

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

Superior

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

Overall, the expected clinical claim is that relative to OMT, TEER is:

- Superior with respect to change in TR severity.
- Superior with respect to mortality.
- Superior with respect to quality of life.
- Inferior with respect to safety such as procedural complications.

Estimated utilisation

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

Estimate the prevalence and/or incidence of the proposed population

As reported in the PICO for MSAC application 1799 (transcatheter tricuspid valve replacement in patients with severe, symptomatic tricuspid regurgitation), the prevalence of moderate or worse TR is estimated to be 2.6% in adults aged 65 years and above (Cahill 2021). Based on the size of the Australian population in 2025 this is approximately 127,780 patients (2.6% x 4,914,620 Australians 65 years or older <https://www.abs.gov.au/statistics/people/population/population-clock-pyramid>). However, only patients with severe, symptomatic TR will potentially be eligible for TEER. Offen (2022) reported on the TR severity of over 400,000 individuals being investigated for heart disease. Of 33,782 people with moderate or worse TR, 7726 (22.9%) had severe disease. This is 29,262 (22.9% x 127,780) patients with severe TR in Australia.

Not all patients with severe TR will be clinically indicated, and eligible for TEER. The proposed population, consistent with the TRILUMINATE Pivotal trial, is most closely aligned with the definition of "pure AF" in Offen (2022) (i.e., without significant pulmonary hypertension or left-sided valvular or ventricular dysfunction). Offen (2022) report that 10.02% (774/7726) of the severe TR population had "pure AF". This is 2,932 (10.02% x 29,262) patients with severe TR who are clinically indicated and suitable for TEER in Australia.

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

Year 1 estimated uptake (%):

REDACTED

Year 2 estimated uptake (%):

REDACTED

Year 3 estimated uptake (%):

REDACTED

Year 4 estimated uptake (%):

REDACTED

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

REDACTED

Will the technology be needed more than once per patient?

No, once only

Consultation

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

Entity who provides the health technology/service:

The Cardiac Society of Australia and New Zealand

Entity who may be impacted by the health technology/service

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

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

Hearts4heart

Entity who produces similar products:

EDWARDS LIFESCIENCES PTY LIMITED

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

Yes

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

Yes

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

Class III

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
373218	TriClip Delivery System - Mitral valve clip
373219	TriClip Steerable Guide Catheter Model Number TSGC0205 - Catheter, intravascular, guiding
401430	TriClip G4 Delivery System - Mitral valve clip
401431	TriClip G4 Steerable Guide Catheter - Catheter, intravascular, guiding
444061	TriClip G4 Clip Delivery System - Mitral valve clip
444062	TriClip Steerable Guide Catheter - Catheter, intravascular, guiding
498645	TriClip G5 Delivery System - Heart valve clip
498646	TriClip G5 Steerable Guide Catheter - Catheter, intravascular, guiding

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

Yes

Codependent details

Will a submission be made to the Prostheses List Advisory Committee (PLAC)?

Yes

Please provide a rationale for the codependency:

Abbott will lodge a Prescribed List Part A application for TriClip following ADAR submission in early 2026.

Are there any other sponsor(s) and / or manufacturer(s) that have similar prosthesis or device component in the Australian market place which this application is relevant to?

Yes

Sponsor/Manufacturer name:

EDWARDS LIFESCIENCES PTY LIMITED

Describe and explain the similarities:

The proposed intervention involves the use of one of two device systems, TriClip™ (Abbott) or PASCAL (Edwards), registered for use in TR in Australia. To note however, and as shown in the Summary of Evidence Section, to date, no randomised controlled trials (RCTs) of the PASCAL system versus OMT in the proposed population exist. A forthcoming RCT comparing TEER using the PASCAL system with OMT (CLASP II TR; NCT04097145) has an expected primary completion date in December 2027. To this end, the comparative the evidence of TEER versus OMT that will be provided in the forthcoming Applicant Developed Assessment Report (ADAR) will pertain to the TriClip device only.

Are there any single and/or multi-use consumables delivered as part of the service or health technology?

Yes

Provide details:

Single-Use Consumables Included:

TriClip System

TriClip Delivery Systems

TriClip Steerable Guide Catheter

Stabilizer