Application for MBS eligible service or health technology

ID:
HPP200086

Application title:
The reduction of mitral regurgitation (MR) through tissue approximation using transvenous/transeptal techniques

Submitting organisation:
EDWARDS LIFESCIENCES PTY LIMITED

Submitting organisation ABN:
77098906873

Application description

Succinct description of the medical condition/s:
Mitral regurgitation (MR), also known as mitral insufficiency, is a condition in which incompetency of the mitral valve causes abnormal backflow of blood from the left ventricle to the left atrium during the systolic phase of the cardiac cycle. There are two types of MR: degenerative and functional. Degenerative mitral regurgitation (DMR), also known as primary MR, refers to regurgitation resulting from the structural abnormality of the mitral valve leaflets and/or valve apparatus. Mitral regurgitation (MR) is the most common heart valve disorder worldwide (Dziadzko et al., 2018), with a high prevalence in industrialized nations with aging populations. MR is associated with an increased risk for heart failure and death.

Succinct description of the service or health technology:
The proposed health technology is device-agnostic transcatheter mitral valve repair (TMVr). Edwards has developed a catheter-based technique for the delivery of a permanent implant to the mitral valve via transseptal access. The implant clasps the anterior and posterior leaflets around a spacer, thus creating a double orifice and reducing MR. The Edwards PASCAL Transcatheter Valve Repair System addresses some of the limitations of other devices, including: a larger implant with wider paddles to potentially reduce the number of implants required for adequate MR reduction; independent clasp control to address complex anatomies and regurgitant jets; a spacer in the centre of the implant to act as a filler in the regurgitant orifice for reduction of MR; working length that allows manoeuvrability even with higher septal puncture heights; and ergonomic controls similar to other Edwards transcatheter product lines which are already familiar to many interventional cardiologists.

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

Is the applicant organisation the organisation you are representing in the HPP today?
Yes

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

Please select any relevant MBS items.

MBS item number	Selected reason type
21936	Co-claimed item
55126	Co-claimed item
55126	Co-claimed item
55127	Co-claimed item
55127	Co-claimed item
55129	Co-claimed item
55129	Co-claimed item
55134	Co-claimed item
55134	Co-claimed item
55135	Co-claimed item
6082	Prerequisite item
6084	Prerequisite item
61109	Co-claimed item

What is the type of service or health technology?
Therapeutic

PICO Sets

Application PICO sets

PICO set number	PICO set name
1	Reduction of mitral regurgitation (MR) through tissue approximation using transvenous/transeptal techniques

Reduction of mitral regurgitation (MR) through tissue approximation using transvenous/transeptal techniques

Supporting documentation

Document type	File name(s)
Application PICO set documents	PICO Set 1_PASCAL TMVr.docx
Reference list	PICO Set 1_PASCAL TMVr.docx

Population

Describe the population in which the proposed health technology is intended to be used:
The proposed population are patients with moderate to severe, or severe, symptomatic degenerative (primary) mitral valve regurgitation.

Search and select the most applicable Medical condition terminology (SNOMED CT):
Mitral valve regurgitation

Intervention

Name of the proposed health technology:
Transcatheter mitral valve repair

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 proposed comparator is TMVr using MitraClip, as outlined in MBS item 38461. This has previously

been accepted by MSAC in their consideration of Application No 1662.1.
In order to deliver the comparator service, a MDHT meeting is required to assess eligibility for the procedure. The service is delivered in either a hybrid operating room or a catheterisation laboratory, by a multidisciplinary team including echocardiographers, interventional cardiologists or cardiothoracic surgeons, and cardiac anaesthesiologists (Lim, Kar et al. 2019). Procedures are performed with transoesophageal echocardiographic and fluoroscopic guidance under general anaesthesia.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:
Safety Outcomes: Patient mortality (procedural), clinical adverse events, procedure-specific adverse events (implant embolism, chordal rupture, implant detachment, vascular complication needing reintervention)

Clinical Effectiveness Outcomes: Survival, freedom from MR grade 3+ or 4+, clinical measures of benefit (NYHA functional class, quality of life, LVEF function, rehospitalisation for CHF)

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:
N/A, the proposed medical service is not a test.

As a result of the proposed item, patients will be able to receive TMVr using any device currently listed on the ARTG and PL for this indication. This will ensure that patients can receive treatment with the most appropriate device for their cardiac anatomy and permit clinicians the flexibility to decide on the best treatment option.

Proposed MBS items

Proposed Item AAAAA

MBS item number:
38461

Please search and select the proposed category:
THERAPEUTIC PROCEDURES

Please search and select the proposed group:
SURGICAL OPERATIONS

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:
TMVr, by transvenous or transeptal techniques, for permanent coaptation of mitral valve leaflets using one or more Mitraclips™, including intra?operative diagnostic imaging, if: (a) the patient has each of the following risk factors: (i) moderate to severe, or severe, symptomatic degenerative (primary) mitral valve regurgitation (grade 3+ or 4+); (ii) left ventricular ejection fraction of 20% or more; (iii) symptoms of mild, moderate or severe chronic heart failure (New York Heart Association class II, III or

IV); and (b) as a result of a TMVr suitability case conference, the patient has been: (i) assessed as having an unacceptably high risk for surgical mitral valve replacement; and (ii) recommended as being suitable for the service; and (c) the service is performed: (i) by a cardiothoracic surgeon, or an interventional cardiologist, accredited by the TMVr accreditation committee to perform the service; and (ii) via transfemoral venous delivery, unless transfemoral venous delivery is contraindicated or not feasible; and (iii) in a hospital that is accredited by the TMVr accreditation committee as a suitable hospital for the service; and (d) a service to which this item, or item 38463, applies has not been provided to the patient in the previous 5 years (H) (Anaes.) (Assist.)

Proposed MBS fee:
$1,568.50

Indicate the overall cost per patient of providing the proposed health technology:
$1,568.60

Please specify any anticipated out of pocket costs:
$0.00

Provide details and explain:
We propose a device agnostic MBS item number removing Mitraclip branding from the descriptor.

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):
TMVr is currently funded on MBS specifically for the Mitraclip system. Currently, patients can receive MBS-funded TMVr using the Mitraclip device only.
PASCAL is available in some accredited public hospitals in Australia.

Please provide a cost break down attachment:

Document type	File name(s)
Cost breakdown attachment	Attachment 1 - Cost breakdown attachment TMVr.docx

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)?
Non-inferior

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

Redacted

The application will present 12-month data from the randomised CLASP IID trial. This study was a non-inferiority study designed to assess the clinical effectiveness and safety of the PASCAL system compared to MitraClip.
A pre-specified interim analysis of 180 patients from the CLASP IID study has previously shown that PASCAL met the primary and secondary non-inferiority endpoints compared to MitraClip (Lim, Smith et al. 2022). At 30 days, the rate of MAEs was 3.4% in the PASCAL arm vs 4.8% in the MitraClip arm. The absolute difference in 30-day composite MAE rate was -1.5%, with the one-sided 95% CI upper

bound of 5.1%. This met the pre-specified non-inferiority margin for this endpoint.
Additionally, the study met its primary effectiveness endpoint of 6-month MR severity. The proportion of patients with MR ≤2+ at 6 months was 96.5% for the PASCAL group and 96.8% for the MitraClip group. The absolute difference was -0.3%, and the upper bound of the one-sided 95% CI was -6.2%, within the pre-specified non-inferiority margin.
The current application will present further data from **redacted** patients from CLASP IID. This data will support the claim of non-inferior safety and effectiveness.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:
As this application aims to update existing MBS items 38461 to be device-agnostic, it is expected that the number of persons eligible to receive TMVr will be equal to those eligible for MitraClip under the current listing. In 2022, 140 patients received treatment for DMR under MBS item 38461. From January to July 2023, there were 73 services provided under this item.
In MSAC Application No 1192.3, it was estimated that MitraClip would result in 174 DMR procedures being conducted in Year 1 growing to 333 in Year 5. So far, utilisation has been lower than expected. PASCAL is not expected to result in market increase, it will simply replace MitraClip utilisation.
Redacted

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 3 estimated uptake(%):
redacted

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

Optionally, provide details:

Will the technology be needed more than once per patient?
No, once only

Provide references to support these calculations.

Document type	File name(s)
Estimated utilisation references	PICO Set 1_PASCAL TMVr.docx

Consultation

List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service:

Professional body name:
AUSTRALIAN AND NEW ZEALAND SOCIETY OF CARDIAC AND THORACIC SURGEONS LIMITED

Professional body name:
THE CARDIAC SOCIETY OF AUSTRALIA AND NEW ZEALAND

List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service:

Professional body name:
Hearts 4 Hearts

List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:

Number of organisations listed: 1

Professional body name:
Consumer Health Forum of Australia

List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology:

Professional body name:
ABBOTT AUSTRALASIA PTY LTD

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
329150	Edwards Lifesciences Pty Ltd - Cardiac implantation catheter table
329680	Edwards Lifesciences Pty Ltd - Cardiac implantation catheter holder
342270	Edwards Lifesciences Pty Ltd - PASCAL Transcatheter Valve Repair System – Implant System - Mitral valve clip
342271	Edwards Lifesciences Pty Ltd - PASCAL Transcatheter Valve Repair System – Guide Sheath - Catheter, intravascular, guiding
371670	Edwards Lifesciences Pty Ltd – PASCAL Transcatheter Valve Repair System – PASCAL Ace Implant System – Mitral valve clip
410288	Edwards Lifesciences Pty Ltd – PASCAL Precision System –Implant System – Mitral valve clip
410289	Edwards Lifesciences Pty Ltd – PASCAL Precision System – PASCAL Ace Implant System – Mitral valve clip
410290	Edwards Lifesciences Pty Ltd – PASCAL Precision System – Guide Sheath – Mitral valve clip

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 Medical Devices and Human Tissue Advisory Committee (MDHTAC)?
Yes

Please provide a rationale for the codependency:
An application will be made to the Prescribed List for PASCAL.

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

Please provide the name(s) of the sponsor(s) and / or manufacturer(s):

Sponsor details

Sponsor name:
Abbott Australasia

Manufacturer details

Manufacturer name:
ABBOTT AUSTRALASIA PTY LTD

Describe and explain the similarities:
The proposed comparator is TMVr using MitraClip, as outlined in MBS item 38461. This has previously been considered appropriate by MSAC in Application 1662.1.

Are there any single and/or multi-use consumables delivered as part of the service or health technology?
No