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| **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 |

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| **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. |

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| **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 |

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| **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 |

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| **Please select any relevant MBS items.** |

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| **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 |

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| **What is the type of service or health technology?**Therapeutic |

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| **PICO Sets** |

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| **Application PICO sets** |

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

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

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| **Supporting documentation** |

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

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| **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 |

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| **Intervention** |
| **Name of the proposed health technology:**Transcatheter mitral valve repair  |

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| **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. |

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| **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. |

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| **Proposed MBS items** |

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| **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. |
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| **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. |

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| **Please provide a cost break down attachment:** |

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

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| **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. |

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| **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 |

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| **Provide references to support these calculations.** |

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

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| **Consultation** |

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

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| **Professional body name:**AUSTRALIAN AND NEW ZEALAND SOCIETY OF CARDIAC AND THORACIC SURGEONS LIMITED |
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| **Professional body name:**THE CARDIAC SOCIETY OF AUSTRALIA AND NEW ZEALAND |
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| **List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service:** |

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| **Professional body name:**Hearts 4 Hearts |
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| **List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:** |

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| **Number of organisations listed:** 1 |
| **Professional body name:**Consumer Health Forum of Australia |
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| **List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology:** |

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| **Professional body name:**ABBOTT AUSTRALASIA PTY LTD |
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| **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 |

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| **Please enter all relevant ARTG IDs:** |

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| **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 |

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

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

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| **Sponsor details** |
| **Sponsor name:**Abbott Australasia |
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| **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. |
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| **Are there any single and/or multi-use consumables delivered as part of the service or health technology?**No |

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