Application for MBS eligible service or health technology

ID:
HPP200052

Application title:
Transluminal insertion, management, and removal of an intravascular microaxial blood pump (IMVAD) (Impella®), for patients with refractory cardiogenic shock

Submitting organisation:
ABIOMED AUSTRALIA PTY LTD

Submitting organisation ABN:
72628849356

Application description

Succinct description of the medical condition/s:
Cardiogenic shock is a complex clinical syndrome, a medical life-threatening emergency, with poor prognosis, which occurs when the heart suddenly cannot pump enough blood and oxygen to the brain and other vital organs. It is defined as a state of end-organ hypoperfusion caused by left ventricular, right ventricular, or biventricular myocardial injury resulting in systolic and/or diastolic myocardial pump failure (Kar 2011). It is characterised by a self-propagating cascade of acute, falling cardiac output and hypotension with ensuing compromised end-organ perfusion. Without appropriate intervention, the end result is multi-organ failure and death (National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand 2018 guidelines for the prevention, detection, and management of heart failure in Australia (NHFA CSANZ 2018).

Succinct description of the service or health technology:
Impella is a transluminal microaxial ventricular assist device that is inserted percutaneously or surgically.
The Impella devices have a small microaxial pump (at one end of a thin, flexible catheter) that pumps blood from the left ventricle through an inlet area near the tip and expels blood into the ascending aorta. The other end of the tube is connected to an automated control system outside the body (that controls the pump rate). The Impella technology is part of the latest generation of cardiac assist devices. The device stabilises haemodynamics, unloads the ventricle, augments peak coronary flow, perfuses the end organs, reduces myocardial oxygen demand and allows for recovery of the native heart. It is indicated for clinical use in interventional cardiology and cardiac surgery for supporting the native heart in patients with reduced ventricular function.

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 Prostheses List?
Yes

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

What is the type of service or health technology?
Therapeutic

PICO Sets

Application PICO sets

PICO set number	PICO set name
1	IMVAD for cardiogenic shock

IMVAD for cardiogenic shock

Supporting documentation

Document type	File name(s)
Application PICO set documents	HPP200052_IMVAD for cardiogenic shock_PICO.docx
Reference list	References.docx

Population

Describe the population in which the proposed health technology is intended to be used:
The proposed population for IMPELLA, consistent with the Ratified PICO for Application 1523, includes patients with CS with no evidence of significant anoxic neurological injury. The proposed population for ECPELLA (IMPELLA added to VA-ECMO) includes patients with CS who are on VA-ECMO and require left ventricular unloading. Please refer to PICO set document for more details of the proposed populations.

Search and select the most applicable Medical condition terminology (SNOMED CT):
Cardiogenic shock

Intervention

Name of the proposed health technology:
The insertion, maintenance and removal of a left intravascular microaxial ventricular assist device (IMVAD) (IMPELLA®). When used together with VA-ECMO, the intervention is referred to as ECPELLA.

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:
VA-ECMO is nominated as the comparator to IMVAD in patients with cardiogenic shock. Similarly, when IMVAD is used in conjunction with ECMO, eg, ECPELLA, the nominated comparator is also VA-ECMO with or without surgical venting.

As per the Ratified PICO for Application 1523, the nominated comparator to IMVAD in patients with CS was "standard care (ie pharmacological therapy and/or intra-aortic balloon pump, and/or extracorporeal membrane oxygenation (ECMO), ventricular assist devices)".
However, in their deliberation of Application 1523, "MSAC agreed with the comparators as assessed by ESC – that is:
• for CS, the appropriate comparator was ECMO; although MSAC noted the lack of evidence to

support this, and also considered that the use of IMVAD in conjunction with ECMO would require justification in a narrower population" (Application 1523 PSD November 2019, pg 3).
• "For the CS population… MSAC noted that recent studies have shown that IABP has limited value in this context and is no longer recommended for this indication" (Application 1523 PSD November 2019, pg 4).
To this end, VA-ECMO is the appropriate comparator to Impella.
The proposed population for ECPELLA includes patients in CS who are on VA-ECMO and require unloading of the LV. One of the disadvantages of VA-ECMO is that the oxygenated blood returning to the body flows retrograde in the aorta and, in turn, causes a marked increase in LV afterload, which due to a number of haemodynamic consequences, further compromises the already failing myocardium. These patients on VA-ECMO need LV unloading. The only approach available to physicians that directly vents the LV is surgical venting; however, owing to its passive and complex procedural nature, it is not suitable for all patients, nor is access to expertise universal. To this end, whilst surgical venting represents an option, it is not routinely used in Australia.
To this end, VA-ECMO with or without venting is the appropriate comparator to ECPELLA.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:
N/A this is not a test - for a definition of outcomes, please refer to PICO set document and Ratified PICO for Application 1523. In short, the most relevant patient outcomes include mortality, transition to durable LVAD/heart transplant, major bleeding, stroke and other complications.

Proposed MBS items

Proposed Item AAAAA

MBS item number:

Please search and select the proposed category:
THERAPEUTIC PROCEDURES

Please search and select the proposed group:
MISCELLANEOUS THERAPEUTIC PROCEDURES

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:
Percutaneous insertion of a left-sided intravascular microaxial ventricular assist device by arteriotomy in patients with CS with no evidence of significant anoxic neurological injury

Proposed MBS fee:
$669.55

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

Please specify any anticipated out of pocket costs:
$0.00

Provide details and explain:

Refer to the COSTBREAKDOWN attachment for more detailed costing. The cost per patient quoted here reflect the cost of the consumables (Impella catheter **Redacted** and purge cassette: **Redacted**) and proposed MBS fee for the service ($669.55) - noting that additional in-hospital and management costs will be in addition to this cost, however, common to both patients managed on IMVAD and the comparator, VA-ECMO.
Anticipated out of pocket expenses are unknown; it may reflect 25% of the MBS fee for patients with private health funds that do not cover this MBS item.

Proposed Item BBBBB

MBS item number:

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:
Surgical removal of a left-sided intravascular microaxial ventricular assist device.

Proposed MBS fee:
$1,004.33

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

Please specify any anticipated out of pocket costs:
$0.00

Provide details and explain:
Refer to the COSTBREAKDOWN attachment for more detailed costing. The cost per patient quoted here reflect the cost of the consumables (Impella catheter: **Redacted** and purge cassette: **Redacted**) and proposed MBS fee for the service ($1,004.33) - noting that additional in-hospital and management costs will be in addition to this cost, however, common to both patients managed on IMVAD and the comparator, VA-ECMO.
Anticipated out of pocket expenses are unknown; it may reflect 25% of the MBS fee for patients with private health funds that do not cover this MBS item.

Proposed Item CCCCC

MBS item number:

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:
Surgical removal of a left-sided intravascular microaxial ventricular assist device.

Proposed MBS fee:

$602.60

Indicate the overall cost per patient of providing the proposed health technology:
$602.60

Please specify any anticipated out of pocket costs:
$0.00

Provide details and explain:
Refer to the COSTBREAKDOWN attachment for more detailed costing. For simplicity, the cost per patient quoted here reflect the proposed MBS fee for the service ($602.60) - noting that additional costs may be required for the surgical removal.
Anticipated out of pocket expenses are unknown; it may reflect 25% of the MBS fee for patients with private health funds that do not cover this MBS item.

Proposed Item DDDDD

MBS item number:

Please search and select the proposed category:
THERAPEUTIC PROCEDURES

Please search and select the proposed group:
MISCELLANEOUS THERAPEUTIC PROCEDURES

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:
Management of the device - first day, including management and monitoring of parameters of the controller for a left-sided intravascular microaxial ventricular assist device

Proposed MBS fee:
$521.85

Indicate the overall cost per patient of providing the proposed health technology:
$521.85

Please specify any anticipated out of pocket costs:
$0.00

Provide details and explain:
Anticipated out of pocket expenses are unknown; it may reflect 25% of the MBS fee for patients with private health funds that do not cover this MBS item.

Proposed Item EEEEE

MBS item number:

Please search and select the proposed category:
THERAPEUTIC PROCEDURES

Please search and select the proposed group:
MISCELLANEOUS THERAPEUTIC PROCEDURES

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:
Management of the device - each day after the first day, including management and monitoring of parameters of the controller for a left-sided intravascular microaxial ventricular assist device

Proposed MBS fee:
$121.40

Indicate the overall cost per patient of providing the proposed health technology:
$121.40

Please specify any anticipated out of pocket costs:
$0.00

Provide details and explain:
Anticipated out of pocket expenses are unknown; it may reflect 25% of the MBS fee for patients with private health funds that do not cover this MBS item

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):
The technology is not funded at present.

Please provide a cost break down attachment:

Document type	File name(s)
Cost breakdown attachment	HPP200052_IMVAD for cardiogenic shock_COST BREAKDOWN.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)?
Superior

Please state what the overall claim is, and provide a rationale:
The use of IMPELLA support in patients with CS results in superior effectiveness relative to VA-ECMO with respect to survival and superior safety with respect to bleeding.
The use of ECPELLA support in patients with CS requiring LV unloading results in superior effectiveness with respect to survival compared with VA-ECMO with or without surgical venting and inferior safety.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:
The incidence of cardiogenic shock in Australia is estimated based on Australian Institute of Health and Welfare (AIHW) reported hospital separations for cardiogenic shock across public and private hospitals.
There were 317 separations for cardiogenic shock in 2016-17, increasing to 463 in 2020-21.
However, it is uncertain what proportion of these patients require mechanical circulatory support, e.g., VA-ECMO or IMVAD. As IMVAD is expected to be utilised in a similar population as is currently treated with VA-ECMO, it is considered reasonable to estimate incidence of the condition based on historical VA-ECMO use on the MBS.
MBS item 13834 for first day management of VA-ECMO was utilised 35 times between May 2022 and April 2023 (i.e., the most recent 12-months of Medicare data). It is noted that over the same period,

MBS item 13832 for peripheral cannulation of VA-ECMO was only utilised 17 times. It is unclear as to why peripheral cannulation was utilised less than the first day management of VA-ECMO. However, MBS item 13832 likely reflects an underrepresentation of VA-ECMO utilisation, and therefore utilisation of MBS item 13834 is considered most appropriate for estimating the size of the eligible IMVAD population.
Based on the last 12 months of available Medicare data, the estimated incidence of the eligible population is 35 patients per year.

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 patients

Optionally, provide details:
Refer to UTILISATION ESTIMATES attachment. Mode detailed analysis of utilisation will be provided and justified in the ADAR.

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	HPP200052_IMVAD for cardiogenic shock_UTILISATION ESTIMATES.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 & New Zealand Society of Cardiac & Thoracic Surgeons (ANZSCTS)

Professional body name:
Australian and New Zealand Intensive Care Society (ANZICS)

Professional body name:
Cardiac Society of Australia and New Zealand (CSANZ)

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:
Australian & New Zealand Society of Cardiac & Thoracic Surgeons (ANZSCTS)

Professional body name:
Australian and New Zealand Intensive Care Society (ANZICS)

Professional body name:
Cardiac Society of Australia and New Zealand (CSANZ)

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

Number of organisations listed: 1

Professional body name:
Hearts4Heart

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

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
307717	Ventricular Assist device Impella 5.0 Model 0046-3114 - Intracardiac circulatory assist axial-pump catheter
344062	Ventricular Assist device Impella 2.5 model 0046-3061 - Intracardiac circulatory assist axial-pump catheter
365210	Impella CP with SmartAssist REF 0048-0008 - Intracardiac circulatory assist axial-pump catheter
368070	Introducer Kit For Impella - Vascular introducer kit
379190	Impella CP with SmartAssist Set - Intracardiac circulatory assist axial-pump catheter
386932	Impella 5.5 with SmartAssist - Intracardiac circulatory assist axial-pump catheter Abiomed

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)?
No

Please provide a rationale for the codependency:
The Applicant wishes to tick 'yes', a submission will be made to the PLAC following MSAC deliberation, however, the question that follows does not have PLAC meeting dates in drop down menu, hence can't be completed. As per advice from the HPP support, 'no' is ticked here to be able to lodge the application.

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?
No

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

Provide details:
Single use consumables include the Impella catheter, introducer kit and a purge cassette.