MSAC Application 1749

Insertion of durable ventricular assist device for use as destination therapy

Application for MBS eligible service or health technology

MSAC Application Number:
1749

Application title:
Insertion of durable ventricular assist device (VAD) for use as destination therapy

Submitting organisation:
ABBOTT MEDICAL AUSTRALIA PTY LTD.

Submitting organisation ABN:
73080212746

Application description

Succinct description of the medical condition/s:
Heart failure is a clinical syndrome presenting with symptoms such as breathlessness, ankle swelling and fatigue, that may be associated with signs such as elevated jugular venous pressure, pulmonary crackle and peripheral oedema. Heart failure is caused by structural or functional abnormalities of the heart resulting in increased intracardiac pressure and/or insufficient cardiac output even at rest or during exercise. Selected patients with advanced heart failure that are refractory to standard medical therapy may receive a heart transplant with long-term mechanical circulatory support (MCS) provided whilst awaiting a transplant; those that don't meet criteria for a heart transplant have a poor prognosis of survival. The application is seeking reimbursement of durable ventricular assist device (VAD) in patients who are not eligible for cardiac transplantation for use as destination therapy.

Succinct description of the service or health technology:
The durable VAD is a surgically implanted pump designed to provide MCS to those afflicted with advanced heart failure who are refractory to standard medical therapy. The HeartMate 3 device is a fully magnetic levitation centrifugal pump, that assumes some or all of the workload of the ventricle, thereby restoring the patient's systemic perfusion while palliating the underlying pathology. In the context of destination therapy, the VAD will be implanted and remain with the patient for 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

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?
No

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

What is the nature of the amendment?
An amendment to the patient population under the existing item(s)

Justification for amendment:
Clinically relevant patient population with an unmet clinical need that is not served by the existing MBS items.

Please select any relevant MBS items.

MBS item number	Selected reason type
38615	Expansion or amendment to existing item
38618	Expansion or amendment to existing item

What is the type of service or health technology?
Therapeutic

PICO Set

Durable ventricular assist device for use as destination therapy

Population

Describe the population in which the proposed health technology is intended to be used:
The proposed patient population include those in whom durable ventricular assist device (VAD) is used as destination therapy in the management of a patient with refractory heart failure, despite optimal medical management including device use where appropriate, with INTERMACS profile 1–4, who is not eligible for cardiac transplantation.

Search and select the most applicable medical condition terminology (SNOMED CT):
Refractory heart failure

Intervention

Name of the proposed health technology:
The insertion of a durable VAD, capable of providing mechanical circulatory support (MCS) for at least 6 months, and in the context of destination therapy is considered permanent (ie, for the lifetime of the patient)

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 insertion of durable VAD for use as destination therapy in patients with advanced heart failure, who are not eligible for heart transplant is guideline directed medical therapy (GDMT), also referred to as optimal medical therapy (OMT). By definition, patients with advanced heart failure have continued to progress and present with severe symptoms despite maximum GDMT and device use as appropriate. Patients with advanced heart failure who are not eligible for a heart transplant have no alternate options than to continue management with GDMT.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:
Not relevant to application. VAD is not a test

Here are the outcomes that are relevant to the assessment of durable VAD:

- Mortality
- Stroke
- Procedural complications / adverse events
- Device issues such as pump replacement / device malfunction /pump explanation or permanent deactivation (unless myocardial recovery)
- Serious adverse events
- Functional status (New York Heart Association [NYHA])
- Quality of life
- Re-hospitalisations
- Resource utilisation

Proposed MBS items

Proposed Item AAAAA

MBS item number:
38615

Category:
THERAPEUTIC PROCEDURES

Proposed group:
SURGICAL OPERATIONS

Item descriptor:
See PICO documentation for edits to the current MBS items and additional notes included. In short:

Insertion of a durable left or right ventricular assist device (VAD) capable of providing mechanical circulatory support for at least 6 months, in a VAD Patient for use as:

(a) a bridge to cardiac transplantation in patients with refractory heart failure who are:

(i) currently on a heart transplant waiting list, or

(ii) expected to be suitable candidates for cardiac transplantation following a period of support on the ventricular assist device; or

(xNEW) destination therapy in the management of a patient with refractory heart failure, despite optimal medical management including device use where appropriate, with INTERMACS profile 1–4, who is not eligible for cardiac transplantation; or

(b) acute post cardiotomy support for failure to wean from cardiopulmonary transplantation; or

(c) cardio-respiratory support for acute cardiac failure which is likely to recover with short term support of less than 6 weeks; or

(d) item 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503 applies;

(H) (Anaes.) (Assist.)

Proposed MBS fee:
$1,619.55

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

Please specify any anticipated out of pocket costs:
$404.89

Provide details and explain:
The intention is to expand the MBS item to include use of a durable VAD as destination therapy, targeting those who will benefit the most from treatment (INTERMACS profile 1-4). As outlined in the PICO document, Abbott consulted with local experts to inform the proposed changes. That is, in reviewing the current MBS item codes, some additional proposed changes were suggested, such as the inclusion of the term 'durable' to ensure appropriate use of the MBS code, and the inclusion of a multidisciplinary team to determine eligibility. This is detailed in the PICO document.

Regarding the anticipated out of pocket costs to patients, this is expected to be similar as per current VAD use on the MBS (unknown to the Applicant). For the purpose of this Application, anticipated out of pocket cost is estimated as a minimum amount of $404.89, reflecting 25% of the MBS fee (noting that for most patients the out of pocket costs would likely exceed this).

Regarding the breakdown of costs to inform the overall cost per patient please refer to the Cost Information attachment.

Proposed Item BBBBB
MBS item number: 38618

Category:
THERAPEUTIC PROCEDURES

Proposed group:
SURGICAL OPERATIONS

Item descriptor:
See PICO documentation for edits to the current MBS items and additional notes included. In short:

Insertion of a durable left and right ventricular assist device (VAD) capable of providing mechanical circulatory support for at least 6 months, in a VAD Patient for use as:

(a) a bridge to cardiac transplantation in patients with refractory heart failure who are:

(i) currently on a heart transplant waiting list, or

(ii) expected to be suitable candidates for cardiac transplantation following a period of support on the ventricular assist device; or

(xNEW) destination therapy in the management of a patient with refractory heart failure, despite optimal medical management including device use where appropriate, with INTERMACS profile 1–4, who is not eligible for cardiac transplantation; or

(b) acute post cardiotomy support for failure to wean from cardiopulmonary transplantation; or

(c) cardio-respiratory support for acute cardiac failure which is likely to recover with short term support of less than 6 weeks; or

(d) item 11704, 11705, 11707, 11714, 18260, 33824, 38418, 38806 or 45503 applies;

(H) (Anaes.) (Assist.)

Proposed MBS fee:
$2,018.75

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

Please specify any anticipated out of pocket costs:
$504.69

Provide details and explain:
See PICO documentation for edits to the current MBS items and additional notes included. In short:

The intention is to expand the MBS item to include use of a durable VAD as destination therapy, targeting those who will benefit the most from treatment (INTERMACS profile 1-4). As outlined in the PICO document, Abbott consulted with local experts to inform the proposed changes. That is, in reviewing the current MBS item codes, some additional proposed changes were suggested, such as the inclusion of the term 'durable' to ensure appropriate use of the MBS code, and the inclusion of a multidisciplinary team to determine eligibility. This is detailed in the PICO document.

Regarding the anticipated out of pocket costs to patients, this is expected to be similar as per current VAD use on the MBS (unknown to the Applicant). For the purpose of this Application, anticipated out of pocket cost is estimated as a minimum amount of $504.69, reflecting 25% of the MBS fee (noting that for most patients the out-of-pocket costs would likely exceed this).

Regarding the breakdown of costs to inform the overall cost per patient please refer to the Cost Information attachment.

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):
The VAD is currently funded on the MBS for other patient populations, but there is currently no funding for use as destination therapy.

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:
Insertion of durable VAD in patients who are not eligible for a heart transplant with the intention of destination therapy is associated with superior survival and quality of life relative to OMT.

Insertion of durable VAD for use as destination therapy is associated with superior mortality relative to OMT. The results from the REMATCH study showed that a first-generation durable VAD (HeartMate vented electric device, Thoratec, Pleasanton, Calif) showed superior survival in patients ineligible for heart transplant versus optimal medical management (Rose 2011). The rates of survival at one year were 52% in the device group and 25% in the OMT group ($p=0.002$), and at two years were 23% and 8% ($p=0.09$), respectively. Survival has been shown to improve with later generation durable VADs, with HeartMate 3 having similar survival to that observed from heart transplant (Netuka 2020). MOMENTUM 3 showed the HeartMate3 device to be associated with less frequent need for pump replacement than HeartMate II and was superior with respect t to survival free of disabling stroke or reoperation to replace or remove a malfunctioning device (Mehra 2019). These results confirm HeartMate 3 to offer a superior device technology to that of HeartMate II.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:
The proposed patient population includes patients with advanced heart failure (HF) refractory to optimal medical and device-based therapies and who are not transplant candidates, and who are unlikely to become candidates for transplantation, reflecting a patient population in whom therapy intent is as destination therapy.

Determining the exact size of this patient population based on a 'top down' epidemiological approach is difficult. There are a number of objective and subjective factors, beyond the confirmation of advanced heart failure and ineligibility for heart transplant, that influence a patient eligibility for destination therapy. For example, the exact criteria for relative and absolute contraindications to durable VAD procedure includes assessment beyond the cardiovascular suitability of the patient but also the lung, kidney and liver functioning of a patient and bleeding risk assessment. The assessment also includes psychosocial requirements such as the presence of adequate caregiver support and some programs use

the Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT) score as another measure of psychosocial health (Clancy 2019).

Therefore, a potentially more reliable approach for estimating the incidence of patients that could receive a durable VAD as DT could be based on the relative number of patients receiving VAD as BTT or BTC. Between 2010 and 2020 an average of 30 VAD procedures were funded via the MBS (items 38615, 38618) and in 2021 and 2022 30 and 28 procedures were funded. Current eligibility for VAD on the MBS includes criteria other than BTT or BTC indication, however for the purposes of the application, it is assumed that 100% of procedures are reimbursed on the basis of BTT/BTC and that each procedure is conducted in a unique patient. Thus, it is estimated that there are on average 30 patients receiving a VAD as BTT or BTC in Australia each year.

According to the INTERMACS 2022 annual report, (a US registry established in 2005 with approximately 28,000 patients currently enrolled at more than 200 sites) 50.8% of all LVAD procedures between 2012 and 2021 were DT with 21.9% and 26.9% being BTT or BTC respectively (Yuzefpolskaya 2023; Table 1). It is noted that between 2019 and 2012, DT represented between 73.0% and 81.1%. However, between 2012 and 2017 DT procedure represented on average approximately 49% of VAD procedures per year. It is considered that this earlier period of DT use is more applicable to adoption of DT on the MBS. In Australia, it can be expected that with time the same number of DT procedures will be conducted as BTT and BTC procedures combined (i.e. 50% DT, 50%BTT/C).

Therefore, the addition of VAD as DT on the MBS could be expected to result in up to 30 procedures being conducted on the MBS each year when the indication for DT has been established after several years of being available. Although this assumes that systems of referral to identify patients potentially eligible for DT are similar between the US and Australia. It is important to note that the number of DT procedures that can actually be performed in the Australian setting is currently limited by capacity constraints and expected to be significantly less than the estimate of 30 procedures (see question below for more details).

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

Year 1 estimated uptake(%):
NR

Year 2 estimated uptake(%):
NR

Year 3 estimated uptake(%):
NR

Year 3 estimated uptake(%):
NR

Estimate the number of patients who will utilise the proposed technology for the first full year:
30

Optionally, provide details:

As per above, up to 30 DT procedures could be performed each in year once the indication for DT has been established in the Australia setting.

However, capacity constraints are expected to limit the use of durable VAD as DT. Clinician input indicated that on average an additional 5 durable VAD procedures could be performed at each of the current implant centres in Australia.

Four quaternary hospitals perform adult heart transplants and implant VADs in Australia and while it is now possible to access VAD therapy through the private system the perceived need for co-location with quaternary transplant services remains a limiting factor with few VADs yet to be implanted privately (Prichard 2020). As such the current maximum number of additional VAD procedures that can be performed with the listing of DT would not be expected to exceed [redacted] per annum.

Leakage beyond the eligible population, is not expected to be of concern for the proposed restriction considering that all patient populations indicated for durable VAD within the guidelines are eligible for treatment, that is BTT, BTC and DT. Capacity constraints as discussed above would further limit if not prohibit leakage along with the use of a multidisciplinary team to establish eligibility (as proposed).

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

Consultation

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

List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:
Hearts4heart

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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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?
AIMD

ARTG ID	ARTG name
300895	HeartMate 3 LVAS Implant Kit Model 106524INT - Implantable ventricular circulatory assist system

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