MSAC Application 1772

Single chamber leadless pacing with atrio-ventricular synchronous pacing in patients with bradycardia

Application or referral for other medical service or health technology

MSAC Application Number:
1772

Application title:
Single chamber leadless pacing with atrio-ventricular synchronous pacing in patients with bradycardia

Submitting organisation:
MEDTRONIC AUSTRALASIA PTY LTD

Submitting organisation ABN:
47001162661

Application description

Succinct description of the medical condition/s:
Bradycardia is defined as abnormally slow heart rhythm, as a consequence of the disturbance of the generation or conduction of cardiac electrical activity. AV block occurs when there is partial or complete interruption of impulse transmission from the atrium to the ventricle. Patients with bradycardia due to AV block are indicated for permanent pacing, which works by preventing the heart from beating slower than a predefined rate, by delivering an electrical stimulus to the myocardium when required.

Succinct description of the service or health technology:
The Micra AV leadless pacemaker is a single-chamber implantable transcatheter pacemaker inserted via the femoral vein and implanted directly into the right ventricular myocardium negating the need for transvenous wires. The Micra AV leadless pacemaker uses mechanical sensing of atrial events to provide "AV synchronous" ventricular pacing.

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?
Amendment

What is the nature of the amendment?
Other

Other reason for amendment:

An MBS item already exists, 38372. However, the applicant is seeking inclusion of the Micra AV intracardiac pacemaker on the Prostheses List

Justification for amendment:

An MBS item already exists, 38372. However, the applicant is seeking inclusion of the Micra AV intracardiac pacemaker on the Prostheses List

Please select any relevant MBS items.
38372

What is the type of service or health technology?
Therapeutic

PICO Set

LPM with AV synchrony for AVB in sinus rhythm

Population

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

The proposed patient population for the insertion of a LPM for pacing of the ventricle and sensing of the atrium (Micra AV) includes patients who are indicated for permanent pacing to treat bradycardia due to AV block and who are in sinus rhythm.

Search and select the most applicable medical condition terminology (SNOMED CT):
Bradycardia

Intervention

Name of the proposed health technology:
Insertion of a single chamber, leadless pacemaker providing atrio-ventricular (AV) synchronous pacing

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 the insertion of a LPM providing AV synchronous pacing in the proposed patient population is the insertion of a conventional, dual chamber transvenous pacemaker (TVPM).

The health care resources that are needed to be delivered at the same time as the comparator service are similar to those delivered at the same time as the proposed intervention, and includes anaesthesia, the professional service itself and hospitalisation. The duration of stay is the same for both procedures with patients admitted overnight.

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. The proposed device is not a test. Refer to the PICO set for details of the relevant outcomes for the LPM.

Proposed MBS items

Proposed Item AAAAA

MBS item number:
38372

Proposed category:
THERAPEUTIC PROCEDURES

Proposed group:
SURGICAL OPERATIONS

Proposed item descriptor:
Leadless permanent cardiac pacemaker, single-chamber ventricular, percutaneous insertion of, for the treatment of bradycardia, including cardiac electrophysiological services (other than a service associated with a service to which item 38350 applies) (H)

Multiple Operation Rule

(Anaes.)

Proposed MBS fee:
$830.30

Indicate the overall cost per patient of providing the proposed health technology:
$0.00

Please specify any anticipated out of pocket costs:
$0.00

Provide details and explain:
No changes to existing MBS items are proposed. Details of the MBS item for insertion (38372) is provided above, noting that the following MBS items are also relevant: 38373 (retrieval and replacement) 38374 (retrieval at least 4 weeks after insertion) and 38375 (explantation). No changes to any of the MBS items are sought.

Refer to the Cost Breakdown Attachment for details regarding the overall cost per patient of providing the proposed health technology.

In terms of anticipated out of pocket costs, if Micra AV is listed on the PL at an acceptable benefit the out-of-pocket cost for the device is expected to be $0.

[In the event the patients' health fund does not cover the cost of the procedure, the out-of-pocket costs for patients may reflect 25% of the MBS item fee for the service ($207.58)]

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):
The procedural component (fee for service) of the proposed intervention is already funded via MBS items 38372 (insertion), 38373 (retrieval and replacement) 38374 (retrieval at least 4 weeks after insertion) and 38375 (explantation). The current wordings of these MBS items would allow for insertion of the Micra AV pacemaker for the proposed population, hence no changes to existing MBS items are proposed.

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 expected clinical claim is that relative to standard DC-TVPM, the transcatheter LPM with Micra AV is:

- Superior with respect to safety (complications over the longer term and reinterventions)
- Superior with respect to quality of life
- Non-inferior with respect to efficacy (including mortality)
- Inferior with respect to technical performance (AV synchronicity, all other parameters are expected to be non-inferior)

The LPM (Micra AV) is safer, with reduced complications, and provides superior quality of life to patients compared with the DC-TVPM. This is consistent with the benefits of the Micra VR device, relative to transvenous single-chamber pacemakers (see MSAC Application 1672).

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:
As discussed in the PICO set, the proposed eligibility criteria are in essence:

- Patients must have AV block, AND
- Patients must have normal sinus rhythm.

These patients can be managed by VDD pacing, a ventricular single-lead VDD pacemaker with two floating atrial electrodes for atrial sensing and a ventricular bipolar pacing/sensing electrode. However, the use of the VDD pacemaker technology is no longer relevant in the current Australian clinical practice (Mond 2023 as well as expert opinion from 7 clinicians experienced in the current management of these patients; see further discussion attached). Today, these patients are instead managed with dual-chamber TVPM in DDD mode; this means that the proposed population is a subgroup of the overall patient population considered for the use of dual-chamber TVPM in current clinical practice.

Based on the usage statistics for MBS item 38356 ("insertion, removal or replacement of dual chamber permanent transvenous electrodes"), approximately 8,900 – 9,700 implantation procedures are performed for the dual-chamber TVPM technology each year in Year 1-4. The supplementary analysis using MBS item 38353, adjusted by the proportion of dual-chamber devices reported in Mond (2023), supported these estimates.

A literature review (see an attachment for usage estimates for further details) suggested an eligibility rate for MICRA AV among the current dual-chamber TVPM recipients of up to 35%; translating to approximately 3,100 – 3,400 patients meeting the proposed eligibility criteria each year in Year 1-4.

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?
Yes, multiple times

Over what duration will the health technology or service be provided for a patient?
8-16 years

Optionally, provide details:
It is expected that the proposed medical service be delivered once per patient. However, when the battery life of the LPM expires, a new LPM unit will be inserted into the right ventricle, whilst leaving the original unit in place. Hence, patients who outlive the battery life of the LPM unit will require another service. The current longevity of the LPM (Micra AV1) battery is ~8 to 13 years depending on the mode of pacing, and it is expected by the time the ADAR has been assessed the next generation LPM will have replaced Micra AV1 and the longevity of the battery will have improved to ~16 years.

What frequency will the health technology or service be required by the patient over the duration?
1

Optionally, provide details:
-

Consultation

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

- The 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:

- The Cardiac Society of Australia and New Zealand (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:

-

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
376750	Micra AV MC1AVR1 - Intracardiac pacemaker
391833	Micra AV MC1AVR1 - Intracardiac pacemaker

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

Codependent details

Please provide a rationale for the codependency:
The service component of the proposed technology is already listed on the MBS (MBS item 38372, 38373, 38374 and 38375).

A PL application for the leadless pacemaker implanted during the implantation service will be submitted during the MSAC process.

Are there any other sponsor(s) and / or manufacturer(s) that have similar prosthesis or device component in the Australian marketplace 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:
Micra AV is packaged pre-loaded onto a delivery catheter which is included in the price of Micra AV. A single use introducer (23 French sheath) is also used to insert the Micra device. The introducer was designed for use with the Micra delivery catheter system and is packaged separately. When the single use introducer is used during a Micra implant, it is included in the total price. There will not be any other consumables that would be considered outside of inclusion in the hospital theatre fees.