MSAC Application 1772

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

Applicant: Medtronic Australasia Pty Ltd

PICO Confirmation

Summary of PICO criteria to define question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Table 1 PICO for leadless pacing with the Micra AV in patients who are indicated for permanent pacing to treat bradycardia due to high-grade AV block and who are in sinus rhythm

Component	Description
Population	Patients who are indicated for permanent pacing to treat bradycardia due to paroxysmal or permanent high-grade atrioventricular (AV) block and who are in sinus rhythm. The following criteria also apply: • A dual chamber transvenous pacing system is considered a poor option (e.g. tortuous anatomy, a need to preserve venous access, increased risk of infection) or not deemed necessary for effective therapy. • A right ventricular transcatheter pacing system promoting AV synchrony at rest is acceptable (i.e. atrial pacing or close to 100% AV synchronicity is not required).
Intervention	Insertion of a leadless pacemaker (LPM) into the right ventricle, that promotes AV synchronous pacing (Medtronic Micra AV)
Comparator	Primary: insertion of a conventional, dual chamber transvenous pacemaker (DC-TVPM) Secondary: insertion of a Micra VR LPM (if applicant intends to seek a higher PL benefit for the Micra AV)
Outcomes	**Technical performance** Pacing performance (sensing, impedance, pacing threshold, AV synchronicity, rate-responsiveness) Battery life **Patient-relevant effectiveness** Mortality (all-cause, cardiovascular) Exercise capacity Switch to an alternative device (a different pacemaker or defibrillator) Health-related quality of life Patient satisfaction Any differential outcome by patient characteristics (e.g. age, comorbidities, pacing indications) **Safety** Implant success/failure rates Procedure-related mortality and major complications (acute, chronic) Major device-related complications (device dislodgement, device malfunction, battery failure, device infection, pacemaker-induced arrhythmia) Pacemaker syndrome Device revision, retrieval, replacement, explantation, reintervention rates Any serious adverse events **Healthcare resources** Cost of the device and consumables Procedure-related costs Follow-up evaluation and monitoring costs Costs associated with the management of complications **Cost-effectiveness** **Total Australian Government health care costs (e.g. public/private hospital, PHI, OOP)**

Component	Description
Assessment questions	What is the comparative safety, effectiveness and cost-effectiveness of the insertion into the right ventricle of an LPM promoting AV synchronous pacing (Micra AV) versus the insertion of a conventional DC-TVPM in patients who are indicated for permanent pacing to treat bradycardia due to paroxysmal or permanent high-grade AV block and who are in sinus rhythm, and where a conventional DC-TVPM is considered a poor option or not deemed necessary for effective therapy?

AV = atrioventricular; DC-TVPM = dual chamber transvenous pacemaker; LPM = leadless pacemaker; OOP = patient out-of-pocket; PHI = private health insurer; PL = Prescribed List of Medical Devices and Human Tissue Products.

Purpose of application

An application was received from Medtronic Australasia Pty Ltd by the Department of Health and Aged Care to facilitate the listing of the Micra™ AV leadless pacemaker (LPM) on the Prescribed List of Medical Devices and Human Tissue Products (PL), via the Tier 3 full health technology assessment pathway. The Tier 3 pathway has been nominated because the applicant is intending for Micra AV to be listed on the PL at a higher benefit than the comparator device and an economic model will be required to assess the longer-term costs and benefits to patients beyond the trial period.

The applicant considered the services associated with the proposed use of Micra AV (insertion, retrieval and replacement, retrieval, explantation by open surgical approach) were already listed on the Medicare Benefits Schedule (MBS) (see Proposal for public funding). The applicant intends to apply for PL listing of the Micra AV following MSAC consideration.

While the Micra AV has not been considered by MSAC previously, the Medtronic Micra VR[1] was considered by MSAC at the July 2022 meeting (MSAC application 1672). The services associated with the Micra VR device were subsequently listed on the MBS in November 2023. The same MBS items were proposed by the applicant to be used for the Micra AV device.

The population proposed by the applicant for insertion of the Micra AV includes patients who are indicated for permanent pacing to treat bradycardia due to atrioventricular (AV) block and who are in sinus rhythm.

The applicant claimed that the insertion of the Micra AV in the proposed population would result in superior health outcomes compared to the insertion of a conventional, dual chamber transvenous pacemaker (DC-TVPM). Specifically, the clinical claims are that the Micra AV is:

- non-inferior with respect to efficacy (including mortality)
- superior with respect to quality of life
- superior with respect to safety (complications over the longer term and reinterventions)
- inferior with respect to technical performance for AV synchronicity
- non-inferior with respect to all other parameters for technical performance.

PICO criteria

Population

The proposed population for insertion of the Micra AV is patients who are indicated for permanent pacing to treat bradycardia due to paroxysmal or permanent high-grade AV block and who are in sinus rhythm. The type of AV block (paroxysmal or permanent high grade) was not mentioned in the application but is specified in the Australian Register of Therapeutic Goods (ARTG) indication (see Regulatory status, Table 3).

The following criteria also apply, in line with the ARTG intended purpose for the Micra AV device:

- A dual chamber transvenous pacing system is considered a poor option (e.g. tortuous anatomy, a need to preserve venous access, increased risk of infection) or not deemed necessary for effective therapy.

[1] Australian Register of Therapeutic Goods (ARTG) entry 391832 and 283235.

- A right ventricular transcatheter pacing system promoting AV synchrony at rest is acceptable (i.e. atrial pacing or close to 100% AV synchronicity is not required).

These criteria require a degree of subjective interpretation on behalf of the clinician in terms of determining patient need for the device.

Micra AV is not appropriate for patients who require pacing to the atrium (i.e. patients with sinus bradycardia with or without chronotropic incompetence), or close to 100% AV synchronicity. According to the applicant, patients who do not require close to 100% AV synchronicity are typically older patients who have co-morbidities and with restricted physical activity.

While some patients with paroxysmal or persistent atrial fibrillation (AF) may be suitable for the Micra AV (as per the ARTG intended purpose, Table 3), these patients are excluded from the PICO population.

PASC advised that the PICO population should include patients in sinus rhythm but not with AF. PASC considered that patients who require atrial pacing (i.e. patients with sinus bradycardia with or without chronotropic incompetence) should be excluded, as the Micra AV does not pace the atrium. PASC noted that while defining patients for whom a DC-TVPM was a poor option should be fairly straightforward in clinical practice, the second proposed criteria 'A right ventricular transcatheter pacing system promoting AV synchrony at rest is acceptable' (taken from the ARTG intended purpose) required further refinement.

The applicant's clinical expert advised that not all candidates for Micra AV are elderly and frail. Some younger patients may benefit from a leadless option, particularly those with recurrent infections, on renal dialysis, or with minimal pacing requirements. Insertion of an LPM would allow such patients to avoid lead issues until they no longer have ventricular capacity for further LPMs, then they could revert to a conventional TVPM.

PASC noted the partial overlap in the Micra VR and Micra AV patient populations and considered the additional benefit of the Micra AV over the Micra VR currently unclear. PASC noted that a proportion of patients who were indicated for Micra AV but received Micra VR because Micra AV was not on the PL at the time of implantation might switch to Micra AV if PL-listed. There might also be patients who received Micra VR for reasons like no venous access but might benefit from AV synchrony. PASC therefore advised the ADAR to also present comparative clinical evidence of Micra AV compared to Micra VR, especially in the context of a claim of superiority for reimbursement purposes.

Bradycardia

Bradycardia is an abnormally slow heart rate, defined as less than 60 beats per minute in adults, except for well-trained athletes (NIH 2023). If untreated, it may lead to fatigue, fainting, palpitations, dizziness, heart failure and an increased risk of death. Bradycardia occurs due to a disturbance in the generation or conduction of cardiac electrical activity and can be broadly categorised as stemming from sinus node dysfunction (SND) or AV block. SND and high-degree AV block are the most common indications for a permanent pacemaker (Glikson et al. 2021).

AV block

AV block occurs when there is a delay or disturbance in the transmission of an impulse from the atria to the ventricles due to an anatomical or functional impairment in the conduction system of the heart (Kashou et al. 2023). The disruption may be transient or permanent and can occur at various locations within the conduction system (Kashou et al. 2023).

According to the European Society of Cardiology (ESC) Guidelines on cardiac pacing and cardiac resynchronization therapy (Glikson et al. 2021), and the 2018 American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Rhythm Society (HRS) Guideline on the evaluation and management of patients with bradycardia and cardiac conduction delay (Kusumoto et al. 2019), not all patients with bradycardia due to AV block are indicated for permanent pacing. While the presence or absence of symptoms is a major factor in determining whether a permanent pacemaker is required, other considerations include the site of the AV block, whether the patient has a systemic disease that leads to progressive AV block or higher risk for ventricular arrhythmias, and the potential harms associated with significant amounts of right ventricular pacing (Kusumoto et al. 2019).

Permanent pacing

Permanent pacing works by preventing the heart from beating slower than a predefined rate by delivering an electrical stimulus to the myocardium when required. There are two main types of permanent pacemaker systems – conventional transvenous systems and leadless systems.

Currently available permanent pacemakers are available in two main types: single chamber or dual chamber. The terminology single chamber and dual chamber traditionally refers to both the location of the device hardware, as well as the chambers that the device has a function in (i.e. sensing or pacing).

Pacemakers have various modes of pacing, represented using a generic code known as NBG[2]. The first letter represents the area being paced (A = atrium, V = ventricle, D = dual, O = none), the second letter represents the area being sensed, and the third letter is the response of the pacemaker to sensing (O = none, I = inhibiting, T = triggering, D = dual). The fourth letter is for rate adaptiveness (O = none, R = rate adaptiveness) (Lak and Goyal 2022). According to the 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy (Glikson et al. 2021), selection of the ideal pacing mode involves consideration of the underlying morbidity, the impact of pacing therapy on morbidity, and the potential harmful effect of the chosen pacing modality.

Epicardial pacemakers are an alternative but less commonly used type of pacemaker (NHS 2022). The pacemaker is usually placed under the skin of the abdomen. The leads are attached to the outer surface of the heart (rather than inside the heart's chambers) and are inserted via minimally invasive surgery (thoracotomy, thoracoscopy and robotic techniques) (Glikson et al. 2021).

Referral and work up for permanent pacing

In Australia, patients with symptomatic bradycardia may initially present to the hospital or to a general practitioner, with subsequent referral to a specialist cardiologist. In the lead up to being considered eligible for a permanent pacemaker, evaluation of the patient's history and physical examination is an important component of the medical evaluation, together with a resting electrocardiography (ECG) to document rhythm, rate and conduction, and to screen for structural heart disease or systemic illness (Kusumoto et al. 2019). Further non-invasive testing may include exercise ECG testing, ambulatory ECG, imaging, laboratory testing, genetic testing and sleep apnoea testing. Invasive testing (such as implantable cardiac monitors and electrophysiology studies) may be required in some patients where non-invasive tests are non-diagnostic (Kusumoto et al. 2019).

[2] Nomenclature developed by the North American Society of Pacing and Electrophysiology (NASPE) and the British Pacing and Electrophysiology Group (BPEG).

Estimated size of the proposed population in Australia

The proposed population is a subgroup of the overall patient population considered for the use of a DC-TVPM. Based on the usage statistics for MBS item 38356 (insertion, removal or replacement of dual chamber permanent transvenous electrodes), the applicant estimates that approximately 8,900 – 9,700 implantation procedures will be performed for DC-TVPM each year from 2024 to 2027. Of those, the applicant estimates that up to 35% will be in patients with AV block and normal sinus rhythm, equating to approximately 3,100 – 3,400 patients each year.

Intervention

The proposed intervention is the insertion of an LPM into the right ventricle, that promotes AV synchronous pacing (Micra AV).

There are two types of LPM systems currently available in Australia, both of which are solely indicated for right ventricular pacing: Micra VR (MSAC application 1672) provides VVI pacing[3] and Micra AV (current application) promotes AV synchronous VDD pacing[4].

Notably, the Food and Drug Administration (FDA) has recently approved dual chamber leadless pacing using the AVEIR DR Leadless System developed by Abbott. The system consists of two percutaneously implanted devices, the single-chamber AVEIR VR leadless pacemaker implanted in the right ventricle, and the AVEIR AR single-chamber pacemaker implanted in the right atrium (Ali 2023). No dual chamber LPMs are currently available in Australia.

The Micra VR and Micra AV LPMs are identical in size, mass, appearance, design and implant procedure. Both devices sense the electrical activity of the patient's heart using sensing and pacing electrodes enclosed in a hermetically sealed titanium capsule. Micra AV is considered a dual chamber pacemaker in terms of its functionality and pacing mode (senses the atrium and ventricle, and paces the ventricle), but single chamber in terms of the location of the hardware (ventricle only). From this perspective it is considered novel, as it can sense activity in the atrium without hardware being located in that chamber.

PASC noted the similarities between the Micra devices in terms of size and insertion/retrieval procedures, noting that the Micra AV is an update of the Micra VR with the capability to provide physiological pacing, albeit very limited.

PASC noted that the Micra AV is variably described as single or dual chamber. By strict definition the Micra AV is a VDD pacemaker at heart rates < 100 beats per minute (bpm) and VVIR pacemaker at heart rates > 100 bpm and has more similarities to a single chamber than dual chamber pacemaker.

PASC noted that a truly dual chamber LPM (providing atrial and ventricular pacing) would likely be available in Australia soon, and patients who receive the Micra AV may need to transition to a dual chamber LPM over time.

[3] Nomenclature refers to: V – pacing in the ventricle; V – sensing in the ventricle; I – inhibiting. In this mode, the pacemaker can sense the electrical activity and withhold pacing when not required.

[4] Nomenclature refers to: V – pacing in the ventricle; D – dual chamber sensing (atrium and ventricle); D – dual modes of response (intrinsic atrial activity can inhibit ventricular pacing and trigger an AV delay, possibly maintaining AV synchrony).

The Micra AV is inserted via the femoral vein and implanted directly into the right ventricular myocardium, negating the need for transvenous wires. The device is anchored in the cardiac tissue via four electrically inactive tines. Fluoroscopic guidance is used throughout the procedure to navigate the delivery system, deploy the device, and assess the adequacy of the device fixation in the patient's cardiac tissue.

The Micra AV system contains the implantable device and the delivery catheter system. The delivery catheter is used to carry, deliver and position the device, test device fixation, and recapture and reposition the device if required during the implant procedure. The delivery catheter is compatible with a 7.8 mm (23 Fr) introducer sheath that is 56 cm or longer (such as the Medtronic Micra Introducer, packaged separately).

A standard Medtronic cardiac device programmer is used in conjunction with the Micra AV device. The programmer is applicable to all implantable Medtronic cardiac devices and is not patient-specific. Similar to TVPMs, Micra has traditional remote monitoring capabilities, but it is not capable of Bluetooth monitoring due to its small size.

The Micra AV monitors for bradycardia and AV synchrony by sensing the electrical and mechanical activity in the heart (atrium and ventricle). In response to bradycardia, the device promotes AV synchronous pacing of the right ventricle, based on sensed mechanical activity in the atrium (hence, the patient must be predominantly in sinus rhythm). Mechanical activity in the atrium is sensed by an internal three-axis accelerometer (Medtronic 2020).

The pacing provided by the Micra AV when the patient is at rest is referred to as VDD pacing. During periods of high patient activity (detected by an activity sensor in the device), the Micra AV provides VVIR pacing (Medtronic 2020). In VVIR mode the ventricle is paced if no intrinsic ventricular events are sensed before the current pacing interval ends, and pacing occurs at the sensor rate (Medtronic 2020).

Device-mediated AV synchrony can be limited at high sinus rates (Medtronic 2020). Clinical trials have demonstrated that AV synchrony ranged from 62.7% during fast walking to 81.5% during sitting (Chinitz et al. 2018), and from 69.8% whilst standing to 89.2% at rest, with average AV synchrony remaining ≥ 70% for all manoeuvres in high-degree AV block patients (Steinwender et al. 2020).

According to the Micra AV Device Manual, the projected longevity of the Micra AV battery (based on accelerated battery discharge data and device modelling) is approximately 8 to 13 years, depending on the mode of pacing[5]. Notably, a Micra AV2 has been developed by Medtronic and is reported to have a projected median longevity of 15.6 years (44 percent more than the Micra AV) (Medtronic 2023). The Micra AV2 is also reported to have improved automatic AV synchrony at heart rates between 80 – 100 beats per minute, and reduced tip pressure from the catheter delivery system during implant (Medtronic 2023). The current MSAC application pertains to the Micra AV device – the Micra AV2 is not currently included in the ARTG.

The Micra AV is not intended to be removed at the end of its service life (Medtronic 2020) but remains in situ and a new LPM is inserted in the right ventricle (or alternative pacing approach if there is a change

[5] 8 years = 100% VDD pacing, 60 bpm, pacing threshold 1.5 V, impedance 500 Ω, pulse width 0.24 ms. 13 years = 15% VDD pacing, 70 bpm, pacing threshold 1.5 V, impedance 600 Ω, pulse width 0.24 ms.

in management). Concerns regarding leaving the Micra VR device in situ were raised by both PASC and MSAC in relation to MSAC application 1672. The Public Summary Document (PSD) noted the lack of available data regarding strategies to replace the Micra VR and the implications of leaving devices in situ at the end of their service life.

The applicant was not aware of any research published since MSAC application 1672 regarding the maximum number of Micra devices that may be implanted in the right ventricle but advised that in practice no more than two devices have been implanted in patients. The applicant confirmed that the research cited in MSAC application 1672 by Omdahl et al. (2016) is generalisable to the Micra AV device as it has the same dimensions and implant procedure as the Micra VR. This research demonstrated that three Micra devices could be accommodated in traditional pacing locations in the right ventricle in six human cadaver hearts and one reanimated heart not deemed viable for transplant. The research only quantified physical distances between the devices, and the authors acknowledged that further research was required to determine whether device performance or cardiac function may be altered by having multiple devices in the right ventricle.

The concerns previously raised by PASC and MSAC in relation to end of service life management should be addressed in the assessment report for MSAC application 1772.

The applicant confirmed that the lifespan of the Micra AV is 8 – 13 years; the more the atrial algorithm is used, the shorter the lifespan. The applicant clarified that the device is designed to be left in situ when replaced, and that most patients will require one or two devices in their lifetime, with a small proportion requiring three. The applicant's clinical expert referenced data from the United States indicating that of all patients who require a pacemaker (regardless of type), 70% of patients will only require one pacemaker in their lifetime.

The applicant confirmed that Micra devices can be left in situ for cremation, though it was acknowledged that this is not yet reflected in all local guidelines.

The proposed use of the Micra AV is summarised in Table 2. The applicant confirmed that the lead up to diagnosis of patients and the work up to determine eligibility for a permanent pacemaker will not change as a consequence of the introduction of the proposed intervention. The applicant also confirmed that clinical management does not differ for a patient receiving a second or subsequent LPM, compared to a patient receiving an initial LPM.

The applicant advised PASC that the frequency of follow-up after insertion of a Micra AV is the same as for a TVPM and noted that the Micra AV has remote monitoring capabilities. The applicant's clinical expert advised that follow-up is slightly more demanding for the first few sessions following insertion of the Micra AV device compared with a TVPM.

Table 2 Proposed use of the Micra AV

Criteria	Description
Purpose	The Micra AV is intended to provide rate-responsive bradycardia pacing to the right ventricle and promote AV synchrony based on mechanical sensing of atrial activity, in the proposed patient population.
Referral	General practitioner or non-interventional cardiologist
Mode of delivery	Percutaneous insertion via the femoral vein
Clinical setting	Hospital (public or private) inpatient

Criteria	Description
Prerequisites and training	Providers who intend to perform insertion of a Medtronic Micra LPM undergo online training modules via Medtronic Academy and attend a Medtronic sponsored in-person training course. Training is provided free of charge. Proficiency in femoral venous access and large bore catheter manipulation are recommended prerequisites. Support by a Medtronic Micra technical expert is recommended for at least the first ten implants.
Provider type	Specialist cardiologist (interventional cardiologist, cardiac electrophysiologist) Cardiac surgeon
Procedure-specific equipment/ consumables	Micra AV device Delivery catheter system Single-use introducer Medtronic programmer and software
Required health system resources	The infrastructure required is expected to be the same as is currently required for the Micra VR: Sterile surgical environment, properly equipped and staffed Anaesthesia Fluoroscopy Professional service for implantation of the device Hospitalisation (can be performed as a day procedure though patients are generally admitted overnight)
Frequency of replacement	Variable. According to the applicant the current battery life for the Micra AV is 8 to 13 years depending on the pacing mode. Patients who outlive the battery life and who continue with leadless pacing will require additional devices/services. The number of devices/services required will depend on the length of time the patient requires the Micra AV, and the actual battery life experienced by the patient.

LPM = leadless pacemaker.
Source: MSAC application 1772 and Micra AV Device Manual provided by the applicant.

Funding of the device

The Micra AV is not currently listed on the PL. The Micra VR was listed on the PL in November 2023 (billing code MI516) at a benefit of $10,083.

The current application did not specify the funding source for the Medtronic programmers and software. This should be addressed in the assessment report, and the costs included in the economic evaluation where relevant (as well as the costs for the Micra AV device, delivery catheter system and single-use introducer).

Regulatory status

As of 19 March 2024 there were four individual ARTG entries under GMDN code 60789 (intracardiac pacemaker). Two of these entries were for the Micra AV device (see Table 3). The remaining two entries were for the Medtronic Micra single chamber transcatheter pacing system (Micra VR).

The proposed population in this PICO Confirmation is a subset of the population defined in the ARTG intended purpose for the Micra AV (see Table 3).

Table 3 ARTG summary for the Micra AV and Micra introducer

Product name (sponsor)	ARTG summary	Functional description	Intended purpose
Micra AV MC1AVR1 - Intracardiac pacemaker	**ARTG ID:** 376750 **Start date:** 22/10/2021 **Category:** Medical Device AIMD	MR Conditional dual chamber, transcatheter pacing system with SureScan technology is a programmable cardiac device that monitors and	Transcatheter pacing systems are sterile, single-use only, active implantable medical devices that are implanted in patients by health care professionals trained in cardiology. Transcatheter pacing systems are intended to improve cardiac output, prevent symptoms of and protect against arrhythmias related

Product name (sponsor)	ARTG summary	Functional description	Intended purpose
(Medtronic Australasia Pty Ltd)	**GMDN:** 60789 Intracardiac pacemaker **ARTG ID:** 391833 **Start date:** 5/07/2022 **Category:** Medical Device Class III **GMDN:** 60789 Intracardiac pacemaker	regulates the patient's heart rate by providing rate-responsive bradycardia pacing to the right ventricle and AV synchrony based on the mechanical sensing of atrial activity. The device senses both the electrical activity and the mechanical activity of the patient's heart using sensing and pacing electrodes and an accelerometer enclosed in a titanium capsule.	to cardiac impulse formation or conduction disorders by providing pacing therapy to the heart. Micra AV Model MC1AVR1 is indicated for VDD pacing in patients when a dual chamber transvenous pacing system is considered a poor option or not deemed necessary for effective therapy, and when a right ventricular transcatheter pacing system promoting AV synchrony at rest is acceptable. Conditions when a patient is considered a poor candidate for transvenous pacing may include, but are not limited to, tortuous anatomy, a need to preserve venous access, or increased risk of infection. The device provides AV synchrony at rest and rate responsive (VVIR) pacing during periods of high patient activity. Device-mediated AV synchrony can vary depending on patient condition and activity levels, and it can be limited at high sinus rates. During periods of intermittent AV synchrony, the device will provide ventricular pacing support with an increased potential for pacing rate variability. Micra AV Model MC1AVR1 is indicated for use in patients who have experienced one of the following: · Paroxysmal or permanent high-grade AV block in the absence of AF · Paroxysmal or permanent high-grade AV block in the presence of paroxysmal AF · Paroxysmal or permanent high-grade AV block in the presence of persistent AF when attempts at restoring sinus rhythm are still planned The device is designed to be used only in the right ventricle.
Micra Introducer - Model MI2355A - Cardiovascular device introducer, non-steerable (Medtronic Australasia Pty Ltd)	**ARTG ID:** 221570 **Start date:** 24/03/2014 **Category:** Medical Device Class III **GMDN:** 57941 Cardiovascular device introducer, non-steerable	The Micra introducer is a single-use, disposable, hydrophilically coated sheath that provides a flexible and hemostatic conduit for the insertion of intravascular devices into the venous system to minimize blood loss. The system is comprised of 2 components: a dilator that accommodates a guidewire and an introducer.	The Micra introducer is intended to provide a conduit for the insertion of devices into the venous system and to minimize blood loss associated with such insertions.

AF = atrial fibrillation; AIMD = active implantable medical device; ARTG = Australian Register of Therapeutic Goods; AV = atrioventricular; MR = magnetic resonance.
Source: ARTG Public Summary documents.

Comparator(s)

The comparator proposed by the applicant is the insertion of a conventional DC-TVPM. Conventional DC-TVPMs have a long history of use and have essentially remained unchanged over time with reliance on a pulse generator that is implanted in a subcutaneous pocket (created at time of insertion) in the infraclavicular region of the anterior chest wall, and a connecting transvenous lead system. The pulse

generator produces the electrical activity required to be transmitted to the myocardium, via the electrodes (leads).

According to the applicant's advisory board (seven Australian specialist cardiologists who are experts in the management of this population), patients with AV block who are in sinus rhythm and who are indicated for permanent pacing receive a DC-TVPM with two leads and DDD mode, even if right ventricular pacing alone would be sufficient. This is consistent with the ESC Guidelines that recommend DDD mode as the default pacing option, and VDD mode only when there is a reason to avoid two leads (Glikson et al. 2021). The advisory board indicated that the use of VDD TVPM technology is no longer relevant in current Australian clinical practice. VDD TVPM devices are not currently listed on the PL and are no longer sold in Australia (Mond and Crozier 2019).

In DDD mode, two leads are inserted percutaneously either via subclavian, cephalic or axillary veins, and guided transvenously via the tricuspid valve into the ventricle and atrium. The position of the wire is checked using fluoroscopy. The lead can either be attached passively with tines, which become fixed via granulation tissue formation, or can be actively fixed to the myocardium using a screw. In this mode the ventricle and atrium are sensed and paced. There is also a rate responsiveness function that allows the programmed rate to increase with increased physical activity, such as strenuous exercise, to allow for a compensatory increase in cardiac output.

The applicant claims that current management of these patients using a DC-TVPM with DDD mode means the patients receive 'more pacing' than required for the condition and are implanted with more hardware than necessary. Proposed benefits of using the Micra AV over a DDD DC-TVPM include the lack of leads and generator in the subcutaneous pocket that can cause infections and lead complications, which is particularly important in this typically frail patient population.

According to the applicant, the health care resources required to deliver the comparator service are similar to those required to deliver the Micra AV service (including anaesthesia, the professional service itself and hospitalisation [with patients generally admitted overnight for both procedures]). The frequency of patient monitoring is also the same for patients who receive a TVPM or an LPM.

The November 2023 PL includes 22 separate billing codes for dual chamber pacemakers, ranging in PL benefit from $6,596 to $7,268 (or up to $8,718 for DC-TVPMs with a remote monitoring service). The PL benefit for most leads (electrodes) for TVPMs is $624 to $634 per lead (transvenous, bi-polar, passive or active, steroid, right ventricular/atrial).

The MBS items relevant to the insertion, removal or replacement of a DC-TVPM and leads are summarised in Table 4. Of note, item 38353 can be used for the insertion of either a dual or single chamber pacemaker generator, while item 38356 is specific to the insertion of leads for a dual chamber TVPM. A separate MBS item is available for percutaneous extraction of chronically implanted transvenous leads (MBS item 38358).

Table 4 MBS items associated with a DC-TVPM and leads

Item no.	Description	Fee and benefit
38353	PERMANENT CARDIAC PACEMAKER, insertion, removal or replacement of, not for cardiac resynchronisation therapy, including cardiac electrophysiological services where used for pacemaker implantation Multiple Operation Rule (Anaes.) (See para TN.8.60 of explanatory notes to this Category)[a]	Fee: $281.15 Benefit: 75% = $210.90
38356	DUAL CHAMBER PERMANENT TRANSVENOUS ELECTRODES, insertion, removal or replacement of, including cardiac electrophysiological services where used for pacemaker implantation Multiple Operation Rule (Anaes.) (See para TN.8.60 of explanatory notes to this Category)[a]	Fee: $921.65 Benefit: 75% = $691.25
38358	Extraction of one or more chronically implanted transvenous pacing or defibrillator leads, by percutaneous method, with locking stylets and snares, with extraction sheaths (if any), if: (a) the leads have been in place for more than 6 months and require removal; and (b) the service is performed: (i) in association with a service to which item 61109 or 60509 applies; and (ii) by a specialist or consultant physician who has undertaken the training to perform the service; and (iii) in a facility where cardiothoracic surgery is available and a thoracotomy can be performed immediately and without transfer; and (c) if the service is performed by an interventional cardiologist—a cardiothoracic surgeon is in attendance during the service (H) Multiple Operation Rule (Anaes.) (Assist) (See para TN.8.64, TN.8.214 of explanatory notes to this Category)	Fee: $3,156.85 Benefit: 75% = $2,367.65

no. = number, DC-TVPM = dual chamber transvenous pacemaker.
a TN.8.60: The fees for the insertion of a pacemaker (Items 38350, 38353 and 38356) cover the testing of cardiac conduction or conduction threshold, etc related to the pacemaker and pacemaker function. Accordingly, additional benefits are not payable for such routine testing under Item 38209 or 38212 (Cardiac electrophysiological studies).
Source: MBS online, accessed 12 March 2024.

PASC considered that historically the most appropriate comparator for the Micra AV would have been a VDD TVPM. As there are currently no dedicated VDD TVPMs on the ARTG or the PL, PASC agreed that it is not an appropriate comparator for the current assessment. PASC noted that an LPM may be an option for a subgroup of patients with congenital heart disease who require dual chamber pacing but do not have the facility to place a TVPM via the veins. For these patients, an epicardial pacemaker may be the appropriate comparator; however, there is unlikely to be sufficient evidence to support a clinical or economic assessment in this niche population.

PASC discussed the limited evidence available to demonstrate the superiority of dual chamber over single chamber pacing, particularly in patients with AV block, acknowledging that clinical practice guidelines recommend DDD over ventricular pacing largely to avoid pacemaker syndrome.

PASC noted that the decision regarding the most appropriate comparator would be influenced by the agreed MBS item descriptor for use with the Micra AV (see Proposal for public funding). If the MBS item descriptor is limited to the proposed patient population (in sinus rhythm), PASC agreed that a DC-TVPM would be the most appropriate comparator.

Although the application did not consider the Micra VR as a potential comparator, the ARTG intended purpose for the Micra AV and Micra VR partially overlap, particularly in relation to patients with symptomatic paroxysmal or permanent high-grade AV block in the absence of AF (see Table 5). During the pre-PASC meeting held on 20 February 2024, the applicant confirmed there may be some patients who have been implanted with a Micra VR device (VVI pacing) – because leadless pacing was the best option for them – who would benefit from AV synchronous pacing (VDD pacing). The clinical algorithm presented in MSAC application 1672 (PICO Confirmation, Figure 3) positioned the Micra VR in the same place as the Micra AV in the current clinical algorithm proposed by the applicant. This suggests that the Micra AV may replace some use of the Micra VR, which could be considered a secondary comparator in the subgroup of patients suitable for either device. The applicant confirmed that patients who transition from a Micra VR to a Micra AV would require permanent deactivation of the Micra VR (programmed to 'Device Off') and insertion of a Micra AV device.

The applicant provided additional information regarding the overlap in the ARTG intended purpose for the Micra AV and Micra VR for paroxysmal or permanent high-grade AV block in the absence of AF. The applicant noted that the overlap was a consequence of history and the clinical need for a LPM in these patients at the time when the Micra VR was registered for use, and the Micra AV was not available. The applicant noted that the Micra VR reflects a suboptimal pacing option in these patients, given the lack of sensing in the atrium. The Micra AV is now the preferred leadless option in patients with paroxysmal or permanent high-grade AV block in the absence of AF.

Table 5 Summary of ARTG intended purpose for Micra AV and Micra VR

Micra AV	Micra VR

• VDD pacing in patients when a dual chamber transvenous pacing system is considered a poor option (e.g. tortuous anatomy, a need to preserve venous access, or increased risk of infection) or not deemed necessary for effective therapy.
• When a right ventricular transcatheter pacing system promoting AV synchrony at rest is acceptable.
• Patients who have experienced one of the following:
  ◦ paroxysmal or permanent high-grade AV block in the absence of AF
  ◦ paroxysmal or permanent high-grade AV block in the presence of paroxysmal AF
  ◦ paroxysmal or permanent high-grade AV block in the presence of persistent AF when attempts at restoring sinus rhythm are still planned.
	• Indicated for use in patients who have experienced one or more of the following conditions:
	  ◦ symptomatic paroxysmal or permanent high-grade AV block in the presence of AF
	  ◦ symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy
	  ◦ symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy.

AF = atrial fibrillation; ARTG = Australian Register of Therapeutic Goods; AV = atrioventricular.
Source: ARTG Public Summary documents for ARTG entries 376750, 391833, 391832 and 283235.

PASC noted there would be some patients in whom the Micra AV would replace the Micra VR due to the overlapping indications for use. It was noted that while the main comparator may be a DC-TVPM, for the purpose of PL benefit setting, superiority of the Micra AV over the Micra VR would need to be demonstrated if the applicant intends to seek a higher benefit for the Micra AV than the Micra VR. PASC advised that it will be difficult to show that the limited AV synchrony provided by the Micra AV has significant advantages over no AV synchrony with the Micra VR device and considered that any advantage is likely to be small. PASC noted the benefit of maintaining AV synchrony at rest is unclear.

The application did not address the current treatment options for patients in whom a dual chamber transvenous pacing system is considered a poor option or not deemed necessary for effective therapy (as per the ARTG intended purpose for the Micra AV device). During the pre-PASC meeting, the applicant advised that despite a TVPM being considered a poor option in some patients, a DC-TVPM would still be used for pacing. Where a contraindication exists to a TVPM, the applicant advised that an epicardial pacemaker may be an option, but these systems are rarely used.

Outcomes

The outcomes proposed to assess the clinical claims are summarised in Table 6.

Battery life is an important consideration for the Micra AV as it will determine the number of replacement devices the patient may need in their lifetime. This will impact the financial costs and cumulative risks associated with reintervention for device replacement. Long-term real-world data are preferable to bench testing to support battery life claims.

Major procedure-related or device-related complications are those that resulted in death, permanent loss of device function as a result of mechanical or electrical dysfunction, hospitalisation, prolongation of hospitalisation by at least 48 hours, or system revision.

Major complications related to cardiac perforation are of particular interest given the FDA Letter to Health Care Providers in November 2021 (FDA Letter, 2021). The letter noted that while the risk of cardiac perforation appeared similar for LPM and traditional TVPM implantation, premarket studies of the Medtronic Micra VR suggested that major complications related to cardiac perforation appeared to be more severe for patients who received a Micra VR than those who received a TVPM. Subsequent FDA evaluations of real-world data further supported the findings at the time the letter was published.

Clinical experience with the Micra VR device may be used as supportive evidence for the safety of Micra AV, given these devices are identical in terms of physical dimensions and implant procedure. However, real-world data has shown a significantly higher rate of perforation in patients implanted with Micra AV than in patients implanted with Micra VR, which the study authors attributed to patients implanted with Micra AV being more likely to have risk factors that predispose them to perforation (Crossley et al. 2024).

PASC agreed that it would be reasonable to accept safety data for the Micra VR device in addition to safety data for the Micra AV device, noting that if there is a difference in any safety outcome between the Micra VR and Micra AV, this needs to be addressed in the assessment report.

Table 6 Proposed outcomes

Outcome type	Outcome
Technical performance	Pacing performance (sensing, impedance, pacing threshold, AV synchronicity, rate-responsiveness) Battery life
Patient-relevant effectiveness	Mortality (all-cause, cardiovascular) Exercise capacity Switch to an alternative device (a different pacemaker or defibrillator) Health-related quality of life Patient satisfaction Any differential outcome by patient characteristics (e.g. age, comorbidities, pacing indications)

Outcome type	Outcome
Safety	Procedure-related mortality and major complications (infection, pericardial effusion, pleural effusion, pneumothorax, cardiac tamponade, cardiac perforation, thromboembolism, vascular complications, intra-procedure cardioversion or defibrillation) – acute and chronic Major device-related complications (device dislodgement, device malfunction, battery failure, device infection, pacemaker-induced arrhythmia) Pacemaker syndrome Device revision, retrieval, replacement, explantation, reintervention rates Any serious adverse events Implant success/failure rates
Healthcare resources	Cost of the device and consumables Procedure-related costs (e.g. device and consumables, services, image guidance, post-implantation evaluation; local/general anaesthesia; admitted patient/day hospital patient) Follow-up evaluation and monitoring costs (including device monitoring) Costs associated with the management of complications

AV = atrioventricular.

PASC agreed with the proposed outcomes. Regarding technical performance, PASC noted that it is unclear what measures would be useful to define the effectiveness of rate responsiveness, and this would require consideration in the assessment report. PASC considered battery life – and subsequent interventions for device replacement – important for the Micra AV, given that atrial sensing at lower heart rates would consume more battery than the Micra VR.

In terms of effectiveness outcomes, PASC noted that capturing switch or upgrade to an alternative device is particularly important because patients with normal sinus rhythm at the time of Micra AV insertion may develop chronotropic incompetence and require atrial pacing with a device that has true dual chamber capability.

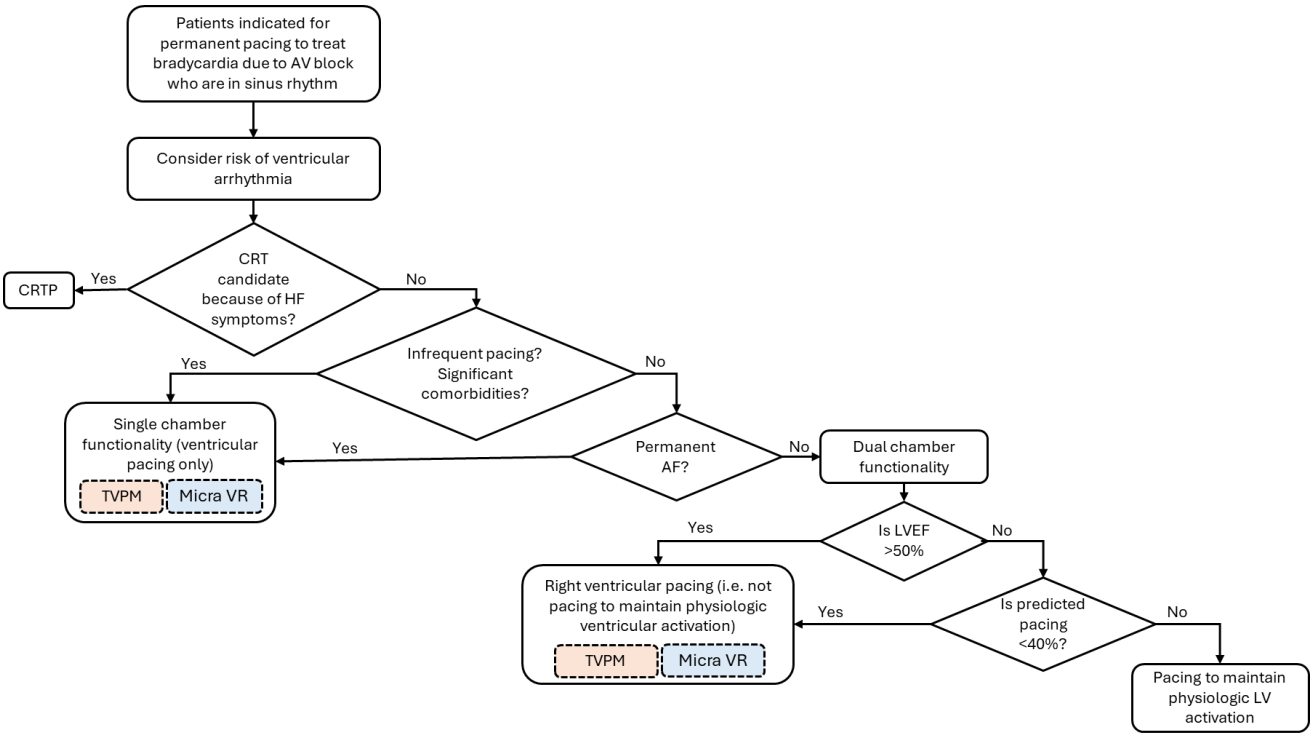
PASC supported the inclusion of pacemaker syndrome, given the benefit of dual chamber over single chamber devices in avoiding this outcome.

PASC noted that data are available to support the superiority of the Micra VR device over a TVPM with respect to safety, although there is a small but serious incidence of cardiac tamponade with LPMs that is not relevant to TVPMs. PASC reiterated that removal of a Micra device is challenging after it has become encapsulated.

Clinical management algorithms

The clinical management algorithm for current practice in the absence of the Micra AV device is shown in Figure 1. This algorithm was adapted from the clinical management algorithm in the ratified PICO Confirmation for MSAC application 1672 (Figure 3). The algorithm was based on joint guidance from the ACC, AHA and the HRS (Kusumoto et al. 2019).

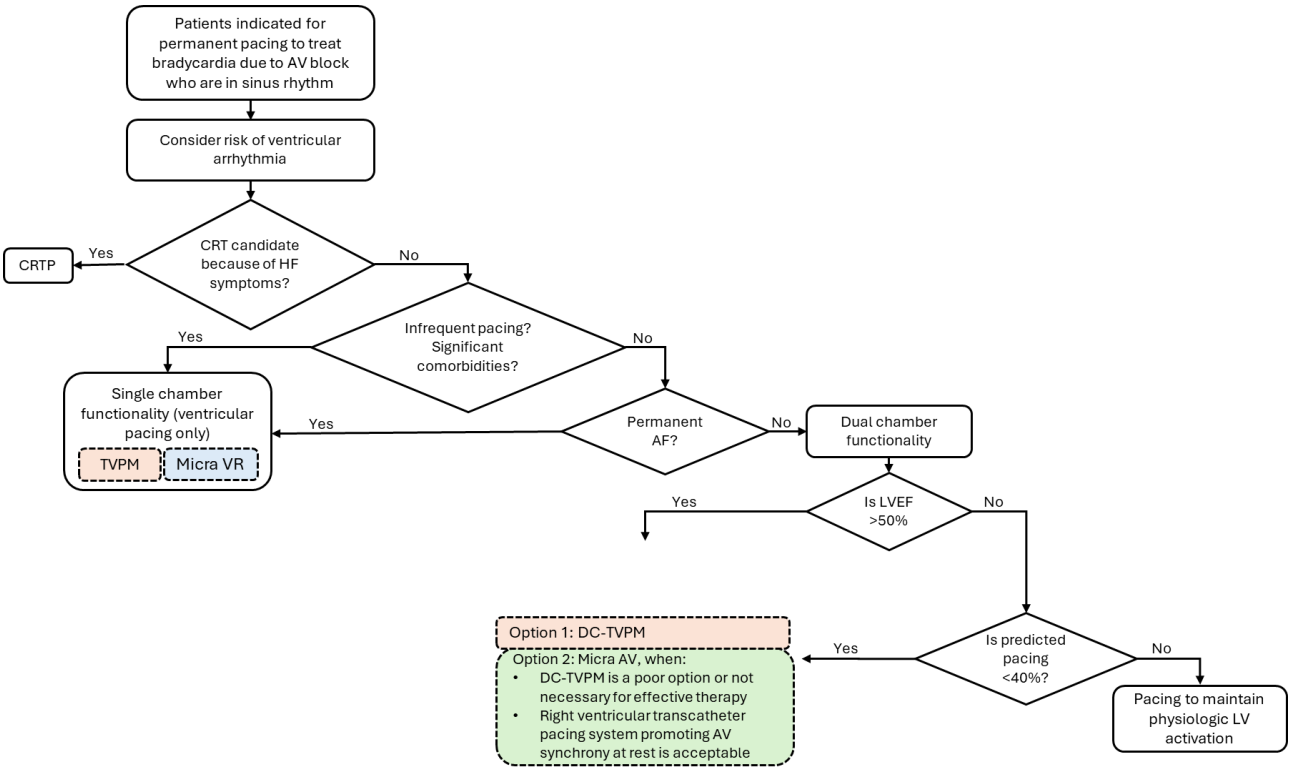
Figure 1 Clinical management algorithm for current practice without the Micra AV



AF = atrial fibrillation; AV = atrioventricular; CRT = cardiac resynchronisation therapy; CRTP = cardiac resynchronisation therapy pacemaker; HF = heart failure; LV = left ventricular; LVEF = left ventricular ejection fraction; TVPM = transvenous pacemaker.
Source: adapted from the clinical management algorithm in the ratified PICO Confirmation for MSAC application 1672 (Figure 3), which was based on the algorithm for management of bradycardia or pauses attributable to chronic AV block (Figure 7) in Kusumoto et al. (2019).

The clinical management algorithm incorporating the Micra AV device is shown in Figure 2. The Micra AV device is indicated for use in patients with AV block and a normal sinus rhythm, and when a right ventricular pacing system is acceptable (i.e. atrial pacing is not necessary). The clinical placement is as an alternative to dual chamber pacing with a TVPM. This algorithm was adapted from the clinical management algorithm prepared by the applicant for the current application (PICO Set, Figure 3). The algorithm is based on joint guidance from the ACC, AHA and the HRS (Kusumoto et al. 2019).

Figure 2 Clinical management algorithm including Micra AV



AF = atrial fibrillation; AV = atrioventricular; CRT = cardiac resynchronisation therapy; CRTP = cardiac resynchronisation therapy pacemaker; DC-TVPM = dual chamber transvenous pacemaker; HF = heart failure; LV = left ventricular; LVEF = left ventricular ejection fraction; TVPM = transvenous pacemaker.
Source: adapted from the clinical management algorithm proposed by the applicant, based on the algorithm for the management of bradycardia or pauses attributable to chronic atrioventricular block in Kusumoto et al. (2019) (Figure 7).

The key difference between the two algorithms is that in Figure 2 the Micra AV replaces the Micra VR as an option for right ventricular pacing in patients indicated for a pacemaker with dual chamber functionality. Figure 2 also provides additional detail regarding when the Micra AV would be considered more appropriate than a DC-TVPM. The applicant claims that the Micra AV will be preferentially considered among patients who do not require near 100% AV synchronicity (typically elderly and those with co-morbidities) and who have a clinical need for a leadless option.

PASC reviewed the clinical algorithms and suggested that guideline-directed management and therapy (GDMT) be changed to cardiac resynchronisation therapy pacemaker (CRTP) in both algorithms. In addition, PASC advised that in both current and proposed algorithms, the starting population should include specification that patients are in sinus rhythm.

Proposed economic evaluation

The application claimed the main benefit of an LPM relative to a TVPM is the elimination of complications associated with TVPMs and leads, such as pocket infections, haematoma, lead dislodgement, and lead fracture. Furthermore, it is claimed that the Micra AV is likely to improve quality of life relative to a DC-TVPM due to earlier return to activities of daily living and hence independence as well as the omission of pain, discomfort and aesthetic issues pertaining to the subcutaneous pocket required for a TVPM.

Based on the applicant's clinical claims of **superior** safety, **non-inferior** efficacy (including mortality) and **superior** quality of life, a cost-utility analysis is appropriate (Table 7).

The assessment report will need to address concerns regarding the strength of the evidence in relation to the claim of superiority given the evidence cited in the application relies on single-arm and real-world studies (direct comparative trials are recruiting).

The key safety evidence appears to be an ongoing 'coverage with evidence development' (CED) study from the United States that uses device registry-linked Medicare claims data (NCT04235491), similar to that used for Micra VR in MSAC application 1672. The primary publication from the Micra AV CED study used propensity score matching to assess complication rates (including reinterventions) and all-cause mortality in Medicare beneficiaries implanted with a Micra AV compared with a contemporaneous cohort of patients implanted with a DC-TVPM, regardless of pacing indication (Crossley et al. 2024). The application noted that additional unpublished analyses stratified by AF at baseline have been performed as a proxy for 'in sinus rhythm' (no AF) and will be provided in the assessment.

The assessment report will need to address concerns regarding the applicability of this evidence to the PICO population, given that pacing indication and preclusion from transvenous pacing cannot be reliably ascertained from administrative claims data.

It is unclear if there is sufficient evidence upon which to examine the claim of superior quality of life. The summary of evidence provided by the applicant included only one published study that reported quality of life as an outcome (Chinitz et al. 2023). The single-arm study does not provide any comparative data upon which to examine the superiority claim. An additional study assessing quality of life was identified by the applicant as unpublished; the study is currently recruiting participants and is not expected to be complete until August 2025.

PASC noted that the Micra AV would probably not increase the number of patients receiving treatment but would replace use of existing treatment.

PASC agreed that a cost-utility analysis (CUA) was appropriate based on the applicant's clinical claims of superior safety and superior quality of life, noting that data to support superior quality of life would need to be provided for the proposed patient population. PASC raised concerns regarding the limited data currently available to inform the CUA, particularly the lack of randomised controlled trial evidence. PASC noted the mandated CED registry study (with estimated enrolment of 37,000 patients and an estimated completion in mid-2027) will report 2-year survival compared with TVPM, which is very limited given the life of a pacemaker.

The applicant confirmed that the cost of the Micra AV will be included in the assessment report.

Table 7 Classification of comparative effectiveness and safety of the proposed intervention, compared with its main comparator, and guide to the suitable type of economic evaluation

Comparative safety	Comparative effectiveness			
	Inferior	Uncertain[a]	Noninferior[b]	Superior
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior[b]	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	**CEA/CUA**

CEA = cost-effectiveness analysis; CMA = cost-minimisation analysis; CUA = cost-utility analysis.
? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis.
a 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations.
b An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence.

Proposal for public funding

This submission to MSAC has been lodged by the applicant to facilitate the listing of the Micra AV on the PL. The applicant intends to apply for PL listing of the Micra AV device following MSAC consideration. The proposed PL benefit for the Micra AV device was not disclosed in the application but will be required in the assessment report.

The applicant indicated that there are existing MBS items that can be claimed for the services associated with the use of the Micra AV device, without amendment. The items relate to the insertion, retrieval and replacement, retrieval, and explantation via open surgical approach of a leadless permanent cardiac pacemaker (single chamber ventricular) (see Table 8). These items were listed on the MBS in November 2023 and are also applicable to the services associated with the Micra VR device (which is identical to the Micra AV in size, design and implant procedure).

LPM insertion is performed as an inpatient service, either in the public or private hospital setting by specialist cardiologists (interventional cardiologist, cardiac electrophysiologist) or cardiac surgeons in a cardiac catheterisation laboratory or operating room. An overnight stay is generally recommended, although in some cases patients may be released home on the same day as the procedure. The first 24 hours after the procedure is critical in terms of monitoring the patient for adverse events and complications, particularly given the potential risk of bleeding due to the large (23 Fr) sheath.

Table 8 Existing MBS items proposed for use with the Micra AV device

Category 3 – THERAPEUTIC PROCEDURES **Group T8 - Surgical Operations** **Subgroup 6 - Cardio-Thoracic** **Subheading 4 - Miscellaneous Cardiac Procedures**
MBS item 38372 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.) Fee: $830.30 Benefit: 75% = $622.75
MBS item 38373 Leadless permanent cardiac pacemaker, single-chamber ventricular, percutaneous retrieval and replacement of, including cardiac electrophysiological services, during the same percutaneous procedure, if: (a) the service is performed by a specialist or consultant physician who has undertaken training to perform the service; and (b) if the service is performed at least 4 weeks after the pacemaker was inserted—the service is performed in a facility where cardiothoracic surgery is available and a thoracotomy can be performed immediately and without transfer; and (c) if the service is performed by an interventional cardiologist at least 4 weeks after the pacemaker was inserted—a cardiothoracic surgeon is in attendance during the service; other than a service associated with a service to which item 38350 applies (H) Multiple Operation Rule (Anaes.) Fee: $830.30 Benefit: 75% = $622.75
MBS item 38374 Leadless permanent cardiac pacemaker, single-chamber ventricular, percutaneous retrieval of, if: (a) the service is performed by a specialist or consultant physician who has undertaken training to perform the service; and (b) if the service is performed at least 4 weeks after the pacemaker was inserted—the service is performed in a facility where cardiothoracic surgery is available and a thoracotomy can be performed immediately and without transfer; and (c) if the service is performed by an interventional cardiologist at least 4 weeks after the pacemaker was inserted—a cardiothoracic surgeon is in attendance during the service (H) Multiple Operation Rule (Anaes.) Fee: $830.30 Benefit: 75% = $622.75
MBS item 38375 Leadless permanent cardiac pacemaker, single-chamber ventricular, explantation of, by open surgical approach (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: $3,107.15 Benefit: 75% = $2,330.40

MBS = Medicare Benefits Schedule.
Source: MBS online accessed 01 March 2024.

According to the PSD for MSAC application 1672 (Micra VR):

'MSAC considered there was an unmet clinical need for a subpopulation of those patients for whom a transvenous pacemaker (TVPM) is inappropriate due to inaccessible upper extremity venous system, increased risk of infection or history of venous thrombosis and advised that this subpopulation needed to be defined in the item descriptor.' (p1)

The item descriptor for MBS item 38372 (Table 8) does not specify the population proposed by MSAC for the insertion of a leadless pacemaker.

The population eligible for MBS item 38372 is also broader than the population proposed for the Micra AV device and the PL has no mechanism to restrict use to the population in whom cost-effectiveness is demonstrated.

Of note, the terminology 'single chamber' and 'dual chamber' pre-dates the development of leadless pacemakers, and traditionally refers to both the function and location of the device components. The Micra AV ARTG entries and Device Manual refer to the device as dual chamber while the current application refers to the device as single chamber. The MBS items proposed for use with the Micra AV use the terminology 'single chamber ventricular', confirmed by the Department to refer to single chamber ventricular pacing. There is potential for implementation issues associated with the variable terminology used to describe the Micra AV.

PASC noted concerns regarding the broad nature of the MBS items proposed for use with the Micra AV, and the potential for use of the device beyond the intended population (with consequent cost implications). It was noted that in the United States, more than 30% of all Medtronic single chamber pacemaker implants were now leadless, in contrast to the niche population currently receiving LPMs in Australia.

PASC considered that a new MBS item would be required for the insertion of the Micra AV, specifying that patients must be in sinus rhythm. PASC also recommended an explanatory note be included with the proposed MBS item to indicate the patients in whom the device is not recommended (i.e., sinus bradycardia with or without chronotropic incompetence). It was noted that the creation of a new item with a more restricted patient population would be particularly important if the Micra AV is listed on the PL at a higher benefit than the Micra VR.

PASC considered the existing MBS items for retrieval, replacement and explantation to be appropriate for use with Micra AV.

Regarding MBS fees, PASC considered that any MBS items created for use with Micra AV should have the same fees as the corresponding MBS items used for the Micra VR, noting that insertion, retrieval and explantation procedures are the same for both devices.

Out-of-pocket costs

The applicant has indicated that if the Micra AV device is listed on the PL at an acceptable benefit, it is expected that there will be no out-of-pocket cost for the device for privately insured patients.

The application did not address whether patients require an external remote monitoring unit following implantation of the Micra AV. This should be addressed in the assessment report, and the associated costs considered in the economic evaluation.

The assessment report should also consider potential out-of-pocket costs relating to insertion, retrieval and explantation procedures.

Summary of public consultation input

PASC noted and welcomed consultation input from 2 organisations. The 2 organisations that submitted input were:

- Hearts4heart
- Abbott Medical Pty. Ltd.

The consultation feedback received was mostly supportive with some concerns raised by Abbott, mainly regarding the comparator and service descriptor.

Clinical need and public health significance

The main benefits of public funding received in the consultation feedback included the safe, cost effective, minimally invasive, less lead infections less complicated and faster recovery leadless pacing option in population with AV block in sinus rhythm. Input from Hearts4heart indicated that the patient experience fewer post implant activity restrictions and obstructions to shoulder movement compared to the traditional pacemaker due to smaller size of the Micra device. Input noted the benefit of safety by eliminating lead and pocket complications for the patients with vulnerable conditions like down syndrome, psychiatric conditions or in young active population where lead damage can be detrimental.

Other services like retrieval, replacement and explantation identified in the consultation feedback as being needed to be delivered before or after the intervention has already been listed on the MBS.

Cost information for the proposed medical service

The consultation feedback from Abbott disagreed with service descriptor. It considered TVPM was an inappropriate comparator for several reasons as the Micra AV cannot pace the atrium (sensing only) and is unable to provide AV synchrony above 100 beats per minute.

The consultation feedback was supportive of the proposed fee. The consultation feedback was supportive of the proposed fee assuming the listing of proposed technology under single chamber pacing subcategory (08.04.04).

Additional comments

Input from Abbott indicated that their device Aveir VR single chamber pacemaker that is expandable to dual chamber technology is expected to be approved in Australia in 2024 and provided detailed information. Abbott considered the proposed device should be listed under the single chamber pacemakers subcategory (08.04.04) of the prescribed list (PL). Hearts4Heart input provided consumer experiences on the benefits of the Micra leadless pacemakers and how the procedure was less invasive, enabled them to recovery quickly, live more a more active lifestyle and have a less bothersome device.

Consumer Feedback

PASC noted that limited public consultation feedback was received for this application. Feedback from Hearts 4 Heart was supportive of the proposal. Extensive feedback was received from Abbott, who indicated intention to apply for listing for a dual chamber LPM. PASC discussed the alternative comparator proposed by Abbott, a VDD pacemaker, and agreed that as there are currently no VDD pacemakers on the ARTG or PL, it is not an appropriate comparator for the current assessment.

Next steps

PASC noted the applicant indicated that an application to the PL would be made following consideration by MSAC.

The applicant confirmed that an applicant developed assessment report (ADAR) will be prepared. PASC advised that the ADAR should include detailed costs associated with the implementation of the device, including the proposed PL benefit.

PASC agreed that the assessment should proceed with the proposal to create a new MBS item for insertion of the Micra AV, and potentially new items for retrieval, replacement and explantation if required.

Applicant Comments on Ratified PICO

The applicant had no comments.

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