Australian Government

Department of Health

MSAC Application 1717

Extravascular implantable cardioverter defibrillator (EV-ICD) therapy for patients at risk of ventricular arrhythmia

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Email: hta@health.gov.au
Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation name: Medtronic Australasia Pty Ltd
ABN: 47 001 162 661
Business trading name: Medtronic Australasia Pty Ltd

Primary contact name: REDACTED

Primary contact numbers
Business: **REDACTED**
Mobile: **REDACTED**
Email: **REDACTED**

Alternative contact name: REDACTED

Alternative contact numbers
Business: **REDACTED**
Email: **REDACTED**

2. (a) Are you a lobbyist acting on behalf of an Applicant?

☒ Yes
☐ No

(b) If yes, are you listed on the Register of Lobbyists?

Yes

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Extravascular implantable cardioverter defibrillator (EV-ICD) therapy for patients at risk of ventricular arrhythmia (VA).

4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

Ventricular arrhythmias are abnormal heartbeats that originate from the ventricles. These types of arrhythmias cause the heart to beat too fast, which prevents oxygen-rich blood from circulating to the brain and body and may result in sudden cardiac death (SCD). The most common types of VA are ventricular tachycardia (VT) and ventricular fibrillation (VF).

The main risk factor for developing VA is ischaemic heart disease (IHD); however, genetic cardiac disease, chronic heart failure (CHF) or a prior history of hypertension or myocardial infarction (MI) also increases risk. Symptoms may include palpitations, light-headedness, syncope, dyspnoea, chest pain and cardiac arrest. [1,2] Ventricular arrhythmias increase morbidity and are attributable to approximately half of all sudden cardiac deaths. [1,3]

5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

The role of a conventional implantable cardioverter defibrillation (ICD) is to continuously monitor cardiac rhythms and provide defibrillation (electronic shocks) and/or post-shock bradycardia pacing therapies for the treatment of life-threatening VA.

The transvenous ICD (TV-ICD), which is the most common ICD design used in clinical practice, is associated with vascular injury, cardiac perforation and pneumothorax, and long-term complications include venous obstruction, lead failure and device/lead infection. The EV-ICD is an alternative option to TV-ICD for patients where insertion of a TV-ICD is not ideal or feasible. EV-ICD offers long-term bradycardia pacing and anti-tachycardia pacing (ATP), unlimited pacing time and a small sized generator.

For single-chamber EV-ICDs, a battery-powered pulse generator is implanted in a pouch under the skin near the serratus on the left side. The wire (electrode) runs from the pulse generator to the anterior mediastinum. If an abnormal heart rhythm is detected the device will deliver an electric shock (defibrillation) to restore a normal heartbeat.

6. (a) Is this a request for MBS funding?

☒ Yes
☐ No

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

☐ Amendment to existing MBS item(s)
☒ New MBS item(s)

[1] Al-Khatib, S.M. et al. 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: Executive summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Heart Rhythm. 2018 Oct;15(10):e190-e252.

2 Priori, S.G. et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC). Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC). Eur Heart J. 2015 Nov 1;36(41):2793-2867.

[3] John, R.M. et al. Ventricular arrhythmias and sudden cardiac death. Lancet. 2012 Oct 27;380(9852):1520-9.

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

N/A

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

N/A

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

☐ A new item which also seeks to allow access to the MBS for a specific health practitioner group
☒ A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
☐ A new item for a specific single consultation item
☐ A new item for a global consultation item(s)

(f) Is the proposed service seeking public funding other than the MBS?

☐ Yes
☒ No

(g) If yes, please advise:

N/A

7. What is the type of service:

☒ Therapeutic medical service
☐ Investigative medical service
☐ Single consultation medical service
☐ Global consultation medical service
☐ Allied health service
☐ Co-dependent technology
☐ Hybrid health technology

8. For investigative services, advise the specific purpose of performing the service *(which could be one or more of the following)*:

N/A

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

☐ Pharmaceutical / Biological
☒ Prosthesis or device
☐ No

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

N/A

(b) If yes, please list the relevant PBS item code(s):

N/A

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

N/A

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

N/A

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

☐ Yes
☒ No

(b) If yes, please provide the following information (where relevant):

N/A

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

☐ Yes
☒ No

REDACTED

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?

☐ Yes
☒ No

12. Please identify any single and / or multi-use consumables delivered as part of the service?

Single-use consumables

- Medtronic Epsila EV Model EAZ101 sternal tunneling tool - will deliver the introducer and EV lead into the anterior mediastinum during implant of the EV-ICD system.
- Medtronic Epsila EV Model EAZ201 transverse tunneling tool – will deliver the proximal portion of the EV lead to the device pocket during implant of the EV-ICD system.

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

Type of therapeutic good: Defibrillator for the EV-ICD system
Product Name: Aurora EV-ICD™ MRI SureScan™ DVEA3E4
Manufacturer's name: Medtronic plc
Sponsor's name: Medtronic Australasia Pty Ltd

Type of therapeutic good: EV-ICD quadripolar lead with passive fixation
Product Name: Epsila EV™ MRI SureScan™ EV2401
Manufacturer's name: Medtronic plc
Sponsor's name: Medtronic Australasia Pty Ltd

(b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

☒ Class III (lead and battery)
☐ AIMD
☐ N/A

14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

☐ Yes (If yes, please provide supporting documentation as an attachment to this application form)
☒ No

(b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

☐ Yes (if yes, please provide details below)
☒ No

15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

☐ Yes (if yes, please provide details below)
☒ No

16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

☒ Yes (please provide details below)
☐ No

Estimated date of submission to TGA: **REDACTED**
Proposed indication(s), if applicable:

- The Aurora EV-ICD MRI SureScan Model DVEA3E4 device is indicated for the automated treatment of patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias through the delivery of antitachycardia pacing, cardioversion, and defibrillation therapies.
- The Epsila EV MRI SureScan Model EV2401 extravascular lead is intended for use in the anterior mediastinum for cardioversion and defibrillation when an extravascular implantable cardioverter defibrillator is indicated.

Proposed purpose(s), if applicable:

- The Aurora EV-ICD MRI SureScan Model DVEA3E4 device is a sterile, single-use only, MRI-compatible, extravascular active implantable medical device intended to monitor and regulate the patient's heart rate.
- The Epsila EV MRI SureScan Model EV2401 lead is a sterile, single-use only implantable medical device intended to provide cardiac therapies in the anterior mediastinum with an extravascular implantable cardioverter defibrillator (EV-ICD).

PART 4 – SUMMARY OF EVIDENCE

17. **Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only).** ***Please do not attach full text articles, this is just intended to be a summary.***

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
1	Non-randomised case series - feasibility	Chan, J.Y.S. et al. Novel extravascular defibrillation configuration with a coil in the substernal space: The ASD clinical study. JACC Clin Electrophysiol. 2017 Aug;3(8):905-910.	ASD Prospective, non-randomised, feasibility and safety study of 16 patients scheduled for midline sternotomy or implant of ICD. Primary endpoint was the defibrillation efficacy of a 35 J induced ventricular fibrillation. Other endpoints were procedure/device complications.	https://pubmed.ncbi.nlm.nih.gov/29759788/	April 2018
2	Non-randomised case series - feasibility	Sholevar, D.P. et al. Feasibility of extravascular pacing with a novel substernal electrode configuration: The Substernal Pacing Acute Clinical Evaluation study. Heart Rhythm. 2018 Apr;15(4):536-542.	SPACE Prospective, non-randomized, multicenter, acute feasibility study of 26 patients. The primary objective was to evaluate the feasibility of pacing with an electrophysiology catheter implanted into the extravascular substernal space (anterior mediastinum) in patients undergoing cardiac procedures. Secondary objectives assessed electrogram data and degree of chest wall stimulation observed during substernal pacing.	https://pubmed.ncbi.nlm.nih.gov/29197657/	August 2017
3	Non-randomised case series - feasibility	Boersma, L.V.A. et al. Therapy from a novel substernal lead: The ASD2 Study. JACC Clin Electrophysiol. 2019 Feb;5(2):186-196.	ASD2 Prospective, multicenter, non-randomised, acute feasibility study of 79 patients. Primary endpoint was defibrillation efficacy at implantation and other endpoints included device/procedure adverse events.	https://pubmed.ncbi.nlm.nih.gov/30784689/	Feb 2019

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
4	Non-randomised case series	ANZ Pilot Study NCT03608670 Crozier, I. et al. First-in-Human Chronic Implant Experience of the Substernal Extravascular Implantable Cardioverter-Defibrillator. JACC Clin Electrophysiol. 2020 Nov;6(12):1525-1536. Swerdlow, C.D. et al. Design and Preliminary Results of Sensing and Detection for an Extravascular Implantable Cardioverter-Defibrillator. JACC Clin Electrophysiol. 2021 Apr 22:S2405-500X(21)00215-2.	ANZ Pilot EV-ICD study Prospective, non-randomised ANZ pilot study of 21 patients at 4 centres who received an EV-ICD system. Primary endpoint was defibrillation efficacy at implantation by inducing, detecting, and converting VF episodes. The primary safety endpoint were device/procedure complications that resulted in death, system revision, hospitalisation, prolongation of a hospitalisation, or permanent loss of defibrillation function at 90 days.	https://pubmed.ncbi.nlm.nih.gov/33213813/	Nov 2020

ANZ, Australia & New Zealand; EV-ICD, extravascular implantable cardioverter defibrillator; ICD, implantable cardioverter defibrillator; n, number of patients; PSM, propensity score matched; S-ICD, subcutaneous implantable cardioverter defibrillator; TV-ICD, transvenous implantable cardioverter defibrillator

18. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only).

	Type of study design	Title of research	Short description of research	Website link to research	Date
1.	Non-randomised case series – pivotal study	EV-ICD pivotal study NCT04060680 Crozier, I. et al. The extravascular implantable cardioverter-defibrillator: The pivotal study plan. J Cardiovasc Electrophysiol. 2021 Sep;32(9):2371-2378 (protocol only)	The EV-ICD pivotal study is a prospective, multicenter, single-arm, non-randomised, premarket study to examine the safety and acute efficacy of the EV-ICD system in up to 400 patients with 3.5 years' follow-up. The primary efficacy endpoint is defibrillation success, safety endpoint is freedom from major complications at 6 months post-procedure. Other endpoints include antitachycardia pacing performance, electrical performance, extracardiac pacing sensation, asystole pacing and appropriate and inappropriate shocks.	https://pubmed.ncbi.nlm.nih.gov/34322918/ (protocol only) https://clinicaltrials.gov/ct2/show/study/NCT04060680	Study results expected to be available Q3 2022.
2.	Non-randomised case series – extended safety study	EV-ICD continued access study NCT05049720	Long-term safety study of the EV-ICD system and/or procedure related adverse events for approximately 200 patients. Planned follow-up period: 18 months.	https://clinicaltrials.gov/ct2/show/NCT05049720	Estimated Study Start Date: 01-Nov-2021 Estimated Primary Completion Date: 28-Jul-2023

BMI, body mass index; EV-ICD, extravascular implantable cardioverter defibrillator; ICD, implantable cardioverter defibrillator; n, number of patients; NYHA, New York Heart Association; PSM, propensity score matched; TV-ICD, transvenous implantable cardioverter defibrillator

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

19. **List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

    Cardiac Society of Australia and New Zealand (CSANZ) – statement of clinical relevance to follow

20. **List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

    Cardiac Society of Australia and New Zealand (CSANZ)

21. **List the consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

    Hearts4Heart (letter of support to follow)

22. **List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

    n/a

23. **Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

    Name of expert 1: **REDACTED**

    Telephone number(s): **REDACTED**

    Email address: **REDACTED**

    Justification of expertise: **REDACTED**

    Name of expert 2: **REDACTED**

    Telephone number(s): **REDACTED**

    Email address: **REDACTED**

    Justification of expertise: **REDACTED**

    Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.

PART 6 – POPULATION (AND PRIOR TESTS), INTERVENTION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

24. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality:

Ventricular arrhythmias are potentially fatal and caused by electrical activation originating from an abnormal focus or electrical circuit in the myocardium of the ventricles. Approximately 25% of deaths are attributable to SCD (males: 6.7 per 100,000 person years vs females: 1.4 per 100,000 person years) which is an established consequence of ventricular arrhythmias.[4]

The risk of VT and of consequent SCD varies on the basis of underlying cardiac conditions as well as other medical and genetic predispositions.[5]

25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

The proposed population is patients who are indicated for single-chamber ICD therapy with/without the need for pacing. Specifically, patients who have one of the following: (a) a history of haemodynamically significant ventricular arrhythmias in the presence of structural heart disease; (b) documented high-risk genetic cardiac disease; (c) ischaemic heart disease, with a left ventricular ejection fraction of less than 30% at least one month after experiencing a myocardial infarction and while on optimised medical therapy; (d) chronic heart failure, classified as New York Heart Association class II or III, with a left ventricular ejection fraction of less than 35% (despite optimised medical therapy).[6]

The EV-ICD system provides an alternative for all patients in need of defibrillation therapy and pacing for the treatment of life-threatening VA. EV-ICD therapy may be preferable to TV-ICD therapy for certain patient groups such as patients with high–risk of infection e.g. patients with renal impairment, diabetes, paediatric or small patients or patients with difficult venous anatomy.

A cardiologist or cardiac specialist will assess each patient for suitability for EV-ICD therapy in the clinical setting and the diagnostic tests required are the same as for TV-ICD.

26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

The most common methods for treating VA are antiarrhythmic medications (i.e. beta blockers), ICDs and cardiac ablation surgery.[7] A cardiologist or cardiac specialist will assess each patient for suitability for EV-ICD therapy in the clinical setting and the diagnostic tests required are the same as for TV-ICD. The clinician will select the appropriate defibrillation system based on the necessary functions of that system (defibrillation, pacing, resynchronisation etc.) and risks involved.

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[4] Eckart, R.E. et al. Sudden death in young adults: an autopsy-based series of a population undergoing active surveillance. J Am Coll Cardiol. 2011 Sep 13;58(12):1254-61.

5 Al-Khatib, S.M. et al. 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: Executive summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Heart Rhythm. 2018 Oct;15(10):e190-e252.

[6] NHFA CSANZ Heart Failure Guidelines Working Group et al. National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand: Guidelines for the Prevention, Detection, and Management of Heart Failure in Australia 2018. Heart Lung Circ. 2018 Oct;27(10):1123-1208.

7 Epstein, A. E. et al. ACC/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: executive summary. 2008. Heart Rhythm, 5(6), 934-955.

Tests prior to EV-ICD/TV-ICD implantation include an electrocardiogram and cardiac echocardiogram, possibly cardiac catheterisation, cardiac MRI and cardiac biopsy. Optimal medical and pharmaceutical therapy for chronic heart failure is provided in accordance with Australian clinical practice guidelines.[8]

See Attachment A – Clinical management algorithm attached.

PART 6b – INFORMATION ABOUT THE INTERVENTION

27. Describe the key components and clinical steps involved in delivering the proposed medical service:

EV-ICD system implantation is commonly provided under conscious or general sedation, as is TV-ICD. An anaesthetist may be required to provide the appropriate level of sedation and a chest x-ray with fluoroscopic screening is required.

The battery-powered pulse generator is implanted in a pouch under the skin near the serratus on the left side of the patient. The wire (electrode) runs from the pulse generator to the anterior mediastinum.

The EV ICD System consists of a 33 cm^3 defibrillator capable of delivering up to 40 J of defibrillation energy and multi-lumen epsilon-shaped leads designed for fixation within the substernal space. There are two pace/sense electrodes and two defibrillation coil segments that are electrically coupled during defibrillation to form an 8 cm defibrillation coil. During surgery, the electrodes are orientated to the left to optimise sensing and pacing therapies and the coils are orientated to the right to facilitate defibrillation therapy.

28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

Aurora EV-ICD is trademarked

29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

Patients who are not candidates for TV-ICD including those who have high–risk of infection (e.g. dialysis patients) or have venous occlusions. See Questions 49 and 50 for further information.

30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

It is anticipated that in nearly all cases that EV-ICD would be delivered only once in a lifetime. If the patient requires a new generator (in the event of battery depletion) then the new generator can be connected to the existing EV-ICD lead.

31. If applicable, identify any healthcare resources or other medical services that would need to be delivered <u>at the same time</u> as the proposed medical service:

It is not anticipated that additional resources or medical services would be delivered at the same time, other than those that would occur during the EV-ICD admission.

32. If applicable, advise which health professionals will primarily deliver the proposed service:

An electrophysiology cardiologist or cardiothoracic surgeon must perform the procedure.

33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

The service cannot be delegated.

34. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

MBS funding is only available for cardiothoracic surgeons or electrophysiology cardiologists.

8 NHFA CSANZ Heart Failure Guidelines Working Group et al. National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand: Guidelines for the Prevention, Detection, and Management of Heart Failure in Australia 2018. Heart Lung Circ. 2018 Oct;27(10):1123-1208.

35. If applicable, advise what type of training or qualifications would be required to perform the proposed service, as well as any accreditation requirements to support service delivery:

Cardiothoracic surgeons must have completed the Cardiothoracic Surgery Program and be eligible to be a Fellow of the Royal Australasian College of Surgeons or otherwise qualified to practice cardiothoracic surgery in Australia.

Electrophysiology Cardiologists must have completed the Advanced Training Curriculum in Cardiology and be eligible to be a Fellow of the Royal Australasian College of Physicians or otherwise qualified to practice interventional cardiology in Australia.

Medtronic propose to provide extensive theoretical and practical training in EV-ICD implantation and therapy to implanting physicians.

36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select ALL relevant settings):

- ☒ Inpatient private hospital (admitted patient)
- ☒ Inpatient public hospital (admitted patient)
- ☐ Private outpatient clinic
- ☐ Public outpatient clinic
- ☐ Emergency Department
- ☐ Private consulting rooms - GP
- ☐ Private consulting rooms – specialist
- ☐ Private consulting rooms – other health practitioner (nurse or allied health)
- ☐ Private day surgery clinic (admitted patient)
- ☐ Private day surgery clinic (non-admitted patient)
- ☐ Public day surgery clinic (admitted patient)
- ☐ Public day surgery clinic (non-admitted patient)
- ☐ Residential aged care facility
- ☐ Patient's home
- ☐ Laboratory
- ☐ Other – please specify below

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

The EV-ICD procedure may be provided in either a public or private hospital.

37. Is the proposed medical service intended to be entirely rendered in Australia?

- ☒ Yes
- ☐ No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

38. 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 (including identifying health care resources that are needed to be delivered at the same time as the comparator service):

The TV-ICD is the comparator for EV-ICD given that these devices both have the same functionality, that is, they can deliver electric shocks (defibrillation) and long-term bradycardia pacing and anti-tachycardia pacing (ATP).

The TV-ICD generator is typically implanted in the left shoulder area, near the collarbone, and the lead(s) are fed through a vein into the heart wall. As with the EV-ICD procedure, it is not anticipated that other resources would be required at the same time other than those that are provided during the TV-ICD procedure.

39. Does the medical service (that has been nominated as the comparator) have an existing MBS item number(s)?

☒ Yes (please list all relevant MBS item numbers below)
☐ No

TV lead insertion: Historical MBS items were 38384 and 38390. In July 2021, these MBS item numbers were consolidated and replaced with MBS item 38471.

40. Define and summarise the current clinical management pathway/s that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards, including health care resources):

Patients receiving EV-ICD will receive an echocardiogram every 6 months. Potential complications of EV-ICD are similar to those of TV-ICD and include pain, inappropriate shocks, lead failure and device/lead infection. If these events occur, patients will receive the required treatment and be followed-up. It is also possible that a re-operation will be required, although this is rare. See Attachment A 'Clinical Algorithm'.

41. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

☐ In addition to (i.e. it is an add-on service)
☒ Instead of (i.e. it is a replacement or alternative)

(b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:

It is estimated that as many as 20% of patients may access EV-ICD in Year 1, should the service be included on the MBS. It is also estimated that an additional 5% of patients with VA (not suitable for TV-ICD) will access EV-ICD. Please see Questions 49 and 50 for further information.

42. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service, including variation in health care resources (Refer to Question 39 as baseline):

The clinical pathway will be essentially the same after EV-ICD as it is for TV-ICD therapy. The length of hospital stay and recovery time for EV-ICD lead and generator insertion is expected to be similar to insertion of TV-ICD leads and generators.

As commented above, there is additional training the implanting physicians need to undertake. Medtronic intend to provide extensive theoretical and practical training in EV-ICD implantation and therapy to these physicians.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

43. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

EV-ICD is non-inferior to TV-ICD in patients at risk of VA in terms of overall survival and appropriate shocks.

EV-ICD is superior to TV-ICD in patients at risk of VA in terms of safety (fewer all-cause ICD-related complications and inappropriate shocks).

44. Please advise if the overall clinical claim is for:

☐ Superiority
☒ Non-inferiority

45. List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Safety Outcomes:

Composite of all-cause ICD-related complications and inappropriate shocks

Inappropriate shocks

Serious adverse events

Device-related complications (pocket or lead complications)

Procedure complications

Replacement procedures or conversion to TV-ICD

Clinical Effectiveness Outcomes:

All-cause mortality

Appropriate shocks (to prevent SCD)

Procedure time

Costs (procedure, device, tests, ongoing monitoring)

Quality of life

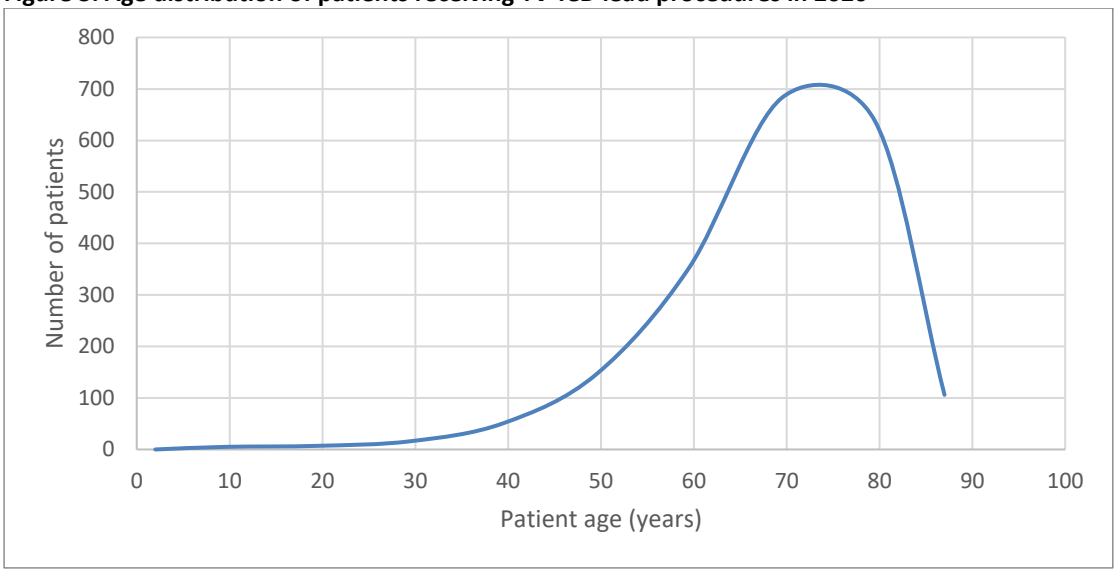
PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

46. Estimate the prevalence and/or incidence of the proposed population:

Prevalence of VA is uncertain due to its spontaneous and variable occurrence[9] although it is known that VA is present in most patients with heart failure, and its severity increases with the severity of heart failure.[10] The incidence of electrical storm is approximately 10 – 30% in patients with VT and an ICD.[11]

The prevalence of patients requiring an ICD is age-dependent. According to Medicare statistics, the mean age of patients undergoing TV-ICD lead procedures (MBS items 38384 and 38390) in 2020 was 69 years and the majority (77%) of these patients were male (Figure 3).

Figure 3. Age distribution of patients receiving TV-ICD lead procedures in 2020[a]



TV-ICD, transvenous implantable cardioverter defibrillator
a. In 2020, TV-ICD lead procedures were captured under MBS items 38384 and 38390. On 1st July 2021, historical MBS items 38384 and 38390 were consolidated and replaced with MBS item 38471.
Source: http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp

The incidence of the population for the proposed EV-ICD lead service is based on the historical MBS use of TV-ICD lead services (MBS items 38384, 38390 and 38471). Note that on 1st July 2021, historical MBS items 38384 and 38390 were consolidated and replaced with MBS item 38471. In 2021, MBS Item 38384, 38390 and 38471 were claimed 725, 475 and 762 times respectively (total = 1,962; Table 1).

The MBS data also show that 1,868 private sector TV-ICD generator implants/replacements/removals were performed in 2021 for MBS items 38387, 38393 and 38472, which roughly correspond to the number of patients undergoing TV-ICD lead services (a proportion will be repeat procedures on the same patient). Note that on 1st July 2021, historical MBS items 38387 and 38393 were consolidated and replaced with MBS item 38472.

The number of private procedures has been slightly decreasing since 2016 (Figure 1 and Figure 2).

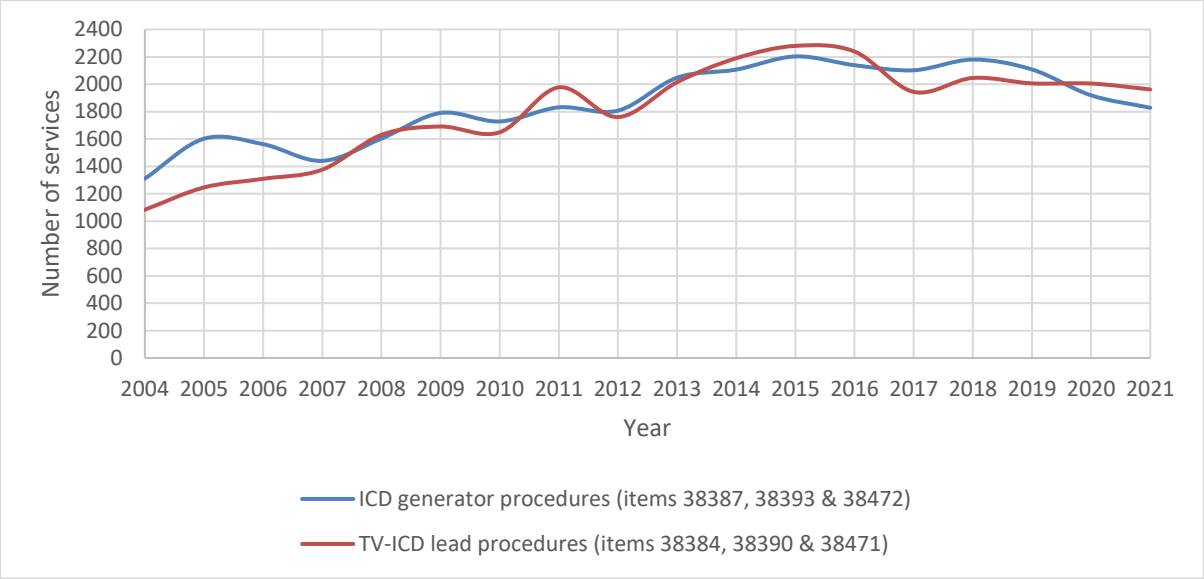
[9] Lip, G.Y. et al. European Heart Rhythm Association/Heart Failure Association joint consensus document on arrhythmias in heart failure, endorsed by the Heart Rhythm Society and the Asia Pacific Heart Rhythm Society. 2015, Eur J Heart Fail, 17(9): 848-874.
[10] Priori, S.G., et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC). Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC). 2015. Eur Heart J, 36(41): 2793-2867.
[11] Geraghty, L. et al. Contemporary management of electrical storm. 2019. Heart Lung Circ, 28: 123-133.

Table 1. MBS service volumes for TV-ICD lead procedures (2016 – 2021)

Service description	MBS item #	2016	2017	2018	2019	2020	2021
Generator Insertion, replacement or removal of implantable defibrillator generator	38387	958	888	979	942	824	463
	38393	1,181	1,214	1,201	1,166	1,095	634
	38472 (new)	-	-	-	-	-	731
	TOTAL	**2,139**	**2,102**	**2,180**	**2,108**	**1,919**	**1,828**
TV leads Insertion of implantable defibrillator, including insertion of patches for the insertion of one or more TV endocardial leads	38384	1323	1119	1209	1198	1,237	725
	38390	916	825	837	808	768	475
	38471 (new)	-	-	-	-	-	762
	TOTAL	**2239**	**1944**	**2046**	**2006**	**2,005**	**1,962**

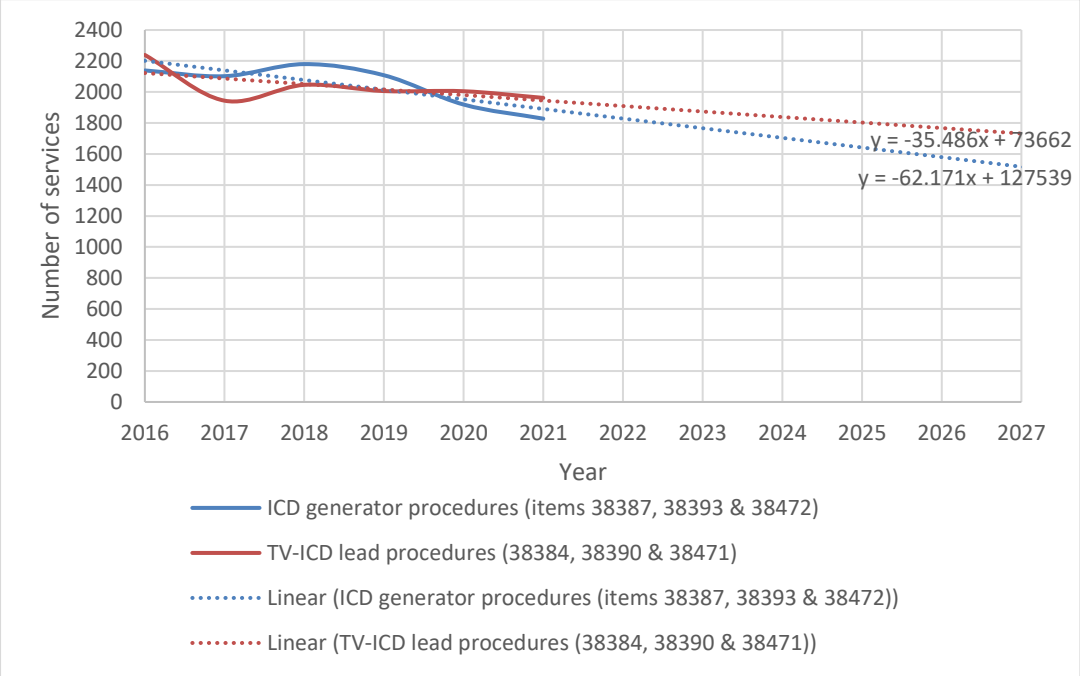
MBS, Medicare Benefits Schedule; TV, transvenous; TV-ICD, transvenous implantable cardioverter defibrillator
Source: http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp (accessed 7th March 2022)

Figure 1. MBS service volumes for ICD generator and TV-ICD lead procedures



ICD, implantable cardioverter defibrillator; MBS, Medicare Benefits Schedule; TV-ICD, transvenous implantable cardioverter defibrillator
Source: http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp (accessed 7th March 2022)

Figure 2. MBS service volumes for ICD generator and TV-ICD lead procedures since 2016 with downward linear trendline



ICD, implantable cardioverter defibrillator; MBS, Medicare Benefits Schedule; TV-ICD, transvenous implantable cardioverter defibrillator
Source: http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp (accessed 7th March 2022)

47. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

As this intervention is usually performed late in life (mean age 69 years for TV-ICD lead procedures as stated for Q46 above), it is anticipated that the service would only be delivered once per patient in their lifetime.

48. How many years would the proposed medical service(s) be required for the patient?

Once in a lifetime. If the patient requires a new generator (in the event battery depletion) then the new generator can be connected to the existing EV-ICD lead.

49. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:

A market-share approach was used to derive the number of patients who will utilise EV-ICD generator and lead services based on the historical MBS use of TV-ICD generator (MBS item 38387, 38393 and 38472) and lead insertion services (MBS items 38384, 38390 and 38471). In 2021, there were 1,828 and 1,962 TV-ICD generator and lead procedures respectively.

The sponsor expects that EV-ICD use is expected to grow the ICD market by **REDACTED** since there is currently a pool of patients who are unsuitable for TV-ICD (e.g., due to structural abnormalities or difficult venous anatomy) or who are reluctant to attempt (or re-attempt) ICD therapy with a transvenous system (e.g., patients who are younger or have comorbidities or who have undergone previous ICD explant).

Assuming an uptake of EV-ICD to start with **REDACTED** of the existing TV-ICD market in Year 1, it is estimated that 394 patients would utilise the proposed EV-ICD lead service in 2023 (Table 2).

Table 2. Determination of forecast service volumes for EV-ICD leads in Year 1 (2023)

	Service utilised (formula)	Actual	Forecast	
		2021	2022	Year 1 2023
A	TV-ICD generator (MBS items 38387, 38393, 38472) (forecast = linear line of best fit for 2016 – 2021 data, y = -62.171x +127,539)[a]	1,828	1,829	**REDACTED**
B	TV-ICD leads (MBS items 38384, 38390, 38471) (forecast = linear line of best fit for 2016 – 2021 data, y = -35.486x+73,662)[a]	1,962	1,909	**REDACTED**
C	Extra proportion of patients suitable for EV-ICD, not TV-ICD	-	-	**REDACTED**
D	Proportion of eligible TV-ICD population suitable for EV-ICD	-	-	**REDACTED**
E	Uptake of EV-ICD	-	-	**REDACTED**
F	EV-ICD generator (A x (1+C) x D x E)			**REDACTED**
G	EV-ICD leads (B x (1+C) x D x E)			**REDACTED**

MBS, Medicare Benefits Schedule; EV-ICD, extravascular implantable cardioverter defibrillator; TV, transvenous implantable cardioverter defibrillator
a. Refer to Figure 2 for formula for line of best fit based on 2016 – 2021 data.
Source: MBS item volumes sourced from Medicare statistics online (accessed 7th March 2022).

50. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:

Insertion/removal/replacement of EV-ICD leads will be performed by the electrophysiology cardiologist or cardiothoracic surgeon in a private or public hospital. It is possible that there will be capacity restraints if there are not enough available facilities and trained medical staff to meet demand. It is likely that capacity will increase in coming years. However, assuming that capacity is available to meet demand, uptake of EV-ICD was assumed to start with **REDACTED** of the existing TV-ICD market in Year 1, increasing to **REDACTED** in Year 2 and **REDACTED** in Year 3 (Table 3).

Table 3. Determination of forecast service volumes for EV-ICD leads (years 1 – 3)

		Year 1 2023	Year 2 2024	Year 3 2025
A	TV-ICD generator (MBS items 38387, 38393, 38472) (forecast = linear line of best fit for 2016 – 2021 data, y = -62.171x +127,539)[a]	**REDACTED**	**REDACTED**	**REDACTED**
B	TV-ICD leads (MBS items 38384, 38390, 38471) (forecast = linear line of best fit for 2016 – 2021 data, y = -35.486x+73,662)[a]	**REDACTED**	**REDACTED**	**REDACTED**
C	ICD market growth given additional proportion of patients suitable for EV-ICD, not TV-ICD	**REDACTED**	**REDACTED**	**REDACTED**
D	Proportion of eligible TV-ICD population suitable for EV-ICD	**REDACTED**	**REDACTED**	**REDACTED**
E	Uptake of EV-ICD	**REDACTED**	**REDACTED**	**REDACTED**
F	EV-ICD generator (A x (1+C) x D x E)	**REDACTED**	**REDACTED**	**REDACTED**
G	EV-ICD leads (B x (1+C) x D x E)	**REDACTED**	**REDACTED**	**REDACTED**

MBS, Medicare Benefits Schedule; EV-ICD, extravascular implantable cardioverter defibrillator; TV, transvenous implantable cardioverter defibrillator
a. Refer to Figure 2 for formula for line of best fit based on 2016 – 2021 data.
Source: MBS item volumes sourced from Medicare statistics online (accessed 7th March 2022).

Since ICD technology is not indicated for other conditions and the proposed population is the same as the TV-ICD and access to EV-ICD is determined by cardiologists or cardiac specialist, it is unlikely that there will be leakage to populations outside the eligible population.

PART 8 – COST INFORMATION

51. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

The sponsor acknowledges that there are some differences between transvenous and extravascular lead placement, however does not expect there are appreciable differences in resource use or procedure times. Therefore, the same MBS service fee (100% fee: $1,095.30, 75% $821.50) is proposed as for TV-ICD lead insertion under MBS item 38471. The overall cost to provide the proposed medical service is $1,785.06 (75% fee, see Table 4).

EV-ICD generators and leads are not currently included on the Prosthesis List (PL), however the sponsor intends to apply for PL listing for the generator and leads.

Table 4. Medical service costs for new MBS item (EV-ICD lead insertion, removal or replacement)

	Cost item	100% MBS Fee	75% Benefit	Source / calculation
A	DFT % of patients tested	100%	100%	Assume 100% of patients require DFT for base case
B	Cost of DFT	$1,428.05	$1,071.05	MBS item 38212 (fee x 100% of patients)
C	Lead placement	$547.65	$410.75	MBS item TBC (fee x 50% with DFT). Same fee as MBS item 38471 for TV leads.
D	Implant of generator	$74.88	$56.16	MBS item 38472 (fee x 25% with DFT)
E	Chest x-ray with fluoroscopic screening	$62.20	$46.25	MBS item 58506
F	Initiation of anaesthesia	$144.20	$108.15	MBS item 21941
G	Anaesthesia Time Units 1:16 to 1:30 hours	$123.60	$92.70	MBS item 23065
	Total medical service costs	**$2,380.58**	**$1,785.06**	**B+C+D+E+F+G**

DFT, defibrillation testing; MBS, Medicare Benefits Schedule; EV-ICD, extravascular implantable cardioverter defibrillator; TV, transvenous
Source: Costs sourced from MBSonline (accessed 14th February 2022)

52. Specify how long the proposed medical service typically takes to perform:

The procedure will typically take 1.25 – 1.75 hours.

53. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

The existing MBS item number 38472 covers insertion, replacement or removal of an implantable defibrillator generator (design agnostic). The generator used for EV-ICD is similar in function and design to the TV-ICD generators, therefore MBS item 38472 is applicable for insertion, replacement and removal of the device.

This application proposes the creation of a new MBS item number for the insertion, removal or replacement of the leads for the EV-ICD system.

Category 3 – Therapeutic Procedures – Surgical Operations
Proposed item descriptor: EXTRAVASCULAR PACING OR DEFIBRILLATOR LEAD, insertion, removal or replacement, if the patient has one of the following: (a) a history of haemodynamically significant ventricular arrhythmias in the presence of structural heart disease; (b) documented high-risk genetic cardiac disease; (c) ischaemic heart disease, with a left ventricular ejection fraction of less than 30% at least one month after experiencing a myocardial infarction and while on optimised medical therapy; (d) chronic heart failure, classified as New York Heart Association class II or III, with a left ventricular ejection fraction of less than 35% (despite optimised medical therapy); other than a service to which item 38212 applies (H) **Fee: $1,095.30 Benefit: 75% = 821.50** Note: For replacement procedures, this MBS item will be claimed only once during a single procedure to remove and replace an EV lead.